FEDERAL TRADE COMMISSION

16 CFR Part 456

RIN 3084–AB37

Ophthalmic Practice Rules (Eyeglass Rule)

AGENCY: Federal Trade Commission.

ACTION: Final rule.

SUMMARY: The Federal Trade Commission (''FTC'' or ''Commission'') is publishing a final rule to implement amendments to the Ophthalmic Practice Rules (''Eyeglass Rule'' or ''Rule''). These amendments require that prescribing eye care practitioners 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 is permitting prescribers to comply with automatic prescription release via electronic delivery if they first obtain verifiable affirmative consent from the patient and maintain a record of such consent for a period of not less than three years. The amendments further 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. Finally, the Commission amends the term ''eye examination'' to ''refractive eye examination'' throughout the Rule.

DATES: This rule is effective September 24, 2024.

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SUPPLEMENTARY INFORMATION:

Statement of Basis and Purpose

Table of Contents

I. Background

A. Overview of the Eyeglass Rule

The Eyeglass Rule (16 CFR part 456) declares it an unfair practice for an optometrist or ophthalmologist to fail to provide a patient with a copy of the patient's eyeglass prescription immediately after an eye examination is completed.[1] The prescriber may not charge the patient any fee in addition to the prescriber's examination fee as a condition of releasing the prescription to the patient.[2] 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.[3]

The Rule prohibits an optometrist or ophthalmologist from conditioning the availability of an eye examination on a requirement that the patient agree to purchase ophthalmic goods from the ophthalmologist or optometrist.[4] The Rule also prohibits the prescriber from placing on the prescription, or requiring 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.[5]

The Rule was implemented after findings that many consumers were being deterred from comparison shopping for eyeglasses because eye care practitioners would not release prescriptions, even when requested to do so, or charged an additional fee for release of the prescription. The Rule's operative provision, which requires prescription release and prohibits fees and waivers for prescription release, is entitled ''Separation of Examination and Dispensing.'' [6] Keeping the exam process and prescription separate from the retail sale of eyeglasses is the key underpinning of the Rule.

B. Background of Prescribers' Failure To Release Prescriptions and the Commission's Automatic-Release Remedy

The FTC has been regulating the optical goods industry for more than six decades, and this experience continues to inform and guide the Rule. As early as 1962, the Commission took steps to protect consumers and competition by adopting the ''Guides for the Optical Products Industry,'' declaring it an unfair practice to ''tie in or condition'' refraction services to eyeglass sales when there was a ''reasonable probability'' of harming competition.[7] However, the Guides were not binding, the FTC never sought to enforce them, and prescribers did not comply with them.[8] In light of such non-compliance, on June 2, 1978, the Commission issued the Advertising of Ophthalmic Goods and Services Rule (the ''Eyeglass I Rule''), which, among other things, contained the provision ''Separation of Examination and Dispensing'' requiring prescribers to automatically release prescriptions—regardless of whether or not patients requested them—so as to draw a line between exams and eyeglass sales, and ensure consumers had unconditional access to prescriptions.[9] The Commission found that consumers suffered substantial economic loss and lost opportunity costs due to an inability to comparison-shop for glasses,[10] and that such practices offended public policy and inhibited competition by denying consumers the ability to use available information.[11] The Commission explained that while it considered requiring prescriptions be released only upon request, it chose ''automatic release'' due to consumers' lack of awareness of their prescription rights, and to immunize such rights from an ''evidentiary squabble'' over whether a consumer did or did not request their prescription.[12]

Upon issuance of the Eyeglass I Rule, the American Optometric Association (''AOA'') filed suit, and the D.C. Circuit upheld the automatic-release requirement, finding there was ''extensive'' evidence that withholding prescriptions harmed consumers.[13] The court also noted there was considerable evidence that prescribers used certain practices ''to frighten consumers'' into purchasing from the prescriber.[14]

In 1985, the Commission re-reviewed the Rule and held public hearings, after which FTC staff proposed changing to release-upon-request,[15] due to what staff perceived to be altered market conditions and increased public awareness, and the challenges staff faced trying to enforce the automatic-release provision.[16] According to staff at that time, automatic release had not prevented evidentiary squabbles,[17] but rather increased them, since whether a prescriber released a prescription could not, in most cases, be ascertained without documentary evidence.[18] In contrast, the hearing officer recommended the automatic-release requirement remain in effect, since prescribers were still not releasing prescriptions to consumers.[19] The Commission sided with the presiding officer's recommendation and issued the ''Eyeglass II Rule,'' which preserved automatic release.[20] The Rule was again challenged in court and parts of it were vacated, but not the automatic-release component, which remained lawful and in effect.[21]

In 1997, the Commission again sought input on the Rule's prescription-release requirement but withheld taking action while it evaluated whether contact lenses should be covered by the Rule.[22] That question was resolved by Congress, which passed the Fairness to Contact Lens Consumers Act (''FCLCA''),[23] directing the FTC to issue a separate rule with automatic prescription-release requirements for contact lenses that were similar to those required by the Eyeglass Rule.[24]

When the Commission looked again at the Eyeglass Rule in 2004, it determined that prescribers continued to withhold prescriptions, and consumers were still not sufficiently aware of their rights.[25] The Commission felt that were it to eliminate the automatic-release remedy, even more prescribers might fail to release prescriptions. Due to this, and because the Commission found that prescription-release enhanced consumer choice at minimal cost, the Commission opted to again retain the automatic-release remedy.[26] By retaining the requirement, the Commission also ensured that prescription-release requirements for eyeglasses and contact lenses would be largely aligned.[27]

C. Evidentiary Standard for Promulgating or Amending the Rule

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.[28] When amending or repealing the Rule, the Commission follows the same section 18 procedures governing the adoption of rules [29] and, in doing so, engages in a multi-step inquiry. To make a determination that an act or 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? [30]

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.'' [31] The Commission can find prevalence where information available to it indicates a widespread pattern of conduct.[32] The evidence necessary to answer the aforementioned questions will vary depending on the circumstances of each rulemaking and the characteristics of the industry involved.[33] When inviting public comment, the Commission requests that commenters provide useful factual data, and, in particular, empirical data such as surveys or other methodologically sound quantitative analyses.[34] The Commission may also consider other reliable evidence and input from experts.[35] Documentary and testimonial evidence, and the absence of any substantial or persuasive contrary evidence, may also be considered.[36] Once the Commission finds that an unfair act or practice is prevalent, the Commission has wide latitude in fashioning a remedy, and need only show a ''reasonable relationship'' between the unfair act or practice and the remedy.[37]

D. The Current Eyeglass Rule Review

1. Advance Notice of Proposed Rulemaking

In 2015, as part of a periodic review of its rules and regulations, the Commission simultaneously published notices in the **Federal Register** initiating reviews of both the Eyeglass Rule and the Contact Lens Rule. The Commission published a request for comment (''RFC'') seeking public input on the efficiency, costs, benefits, and regulatory impact of the Contact Lens Rule, including its prescription release requirement.[38] The Commission published an advance notice of proposed rulemaking (''ANPR'') for the Eyeglass Rule inviting comments on, among other things: the continuing need for the Rule; the Rule's economic impact and benefits; and the effect on the Rule of any technological, economic, or other industry changes.[39] The Commission also sought comment on whether: the definition of ''prescription'' should be modified to include pupillary distance, to require that a prescriber provide a duplicate copy of a prescription to a patient who does not have access to the original, and to require that a prescriber provide a copy to or verify a prescription with third parties authorized by the patient.[40]

In response to its Eyeglass Rule ANPR, the Commission received and considered 868 comments from a variety of individuals and entities, including ophthalmologists, optometrists, opticians, trade associations, consumers (and consumer-advocacy representatives), and eyeglass sellers.[41] Virtually all comments supported retaining the Rule. Some commenters, including trade associations representing opticians and retailers who employ optometrists and opticians, stated that the Rule is needed because some prescribers are still not automatically releasing prescriptions, and some consumers face resistance when they try to obtain their prescriptions.[42] The AOA, on the other hand, questioned the continued need for the Rule based on its view that optometrists widely comply with the Rule's requirements, but also commented that the Rule—as currently codified—is not necessarily harmful.[43]

2. The Contact Lens Rule Review

The Commission focused on finalizing changes to the Contact Lens Rule (CLR) before considering amendments to the Eyeglass Rule. During its CLR review, the Commission considered over 8,000 comments and issued both a notice of proposed rulemaking [44] and a supplemental notice of proposed rulemaking [45] (''SNPRM'') before issuing a final rule on August 17, 2020.[46] While the CLR 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.

In its CLR final rule, the Commission determined that the evidentiary record, as well as the Commission's enforcement and oversight experience, demonstrated that prescriber compliance with the automatic-prescription-release requirement was deficient, and as a result, millions of consumers were not receiving their contact lens prescriptions as required by law.[47] The Commission further found that many consumers remained unaware that they have a right to their prescriptions.[48] To remedy this, the Commission implemented a confirmation-of-prescription-release provision, requiring that prescribers request that patients confirm receipt of their contact lens prescription.[49] According to the Commission, the patient confirmation requirement was intended to, among other things, increase the number of patients in possession of their contact lens prescription, improve flexibility and choice for consumers, foster improved competition in the market, and result in lower prices and more efficient contact lens sales for consumers.[50] The Commission noted that the requirement would also increase the Commission's ability to enforce and assess the CLR.[51]

The final CLR included an additional amendment addressing a concern relevant to the Eyeglass Rule review, in that the Commission recognized the value in allowing prescribers to deliver prescriptions to patients digitally, so long as prescribers provide the prescription in a format that can be accessed, downloaded, and printed by the patient, and the patient agrees to receive their prescription in the format identified by the prescriber.[52] The final CLR expressly made this permissible by adding a definition of the term ''provide to the patient a copy'' to allow the prescriber to provide the patient with a digital copy of the prescription in lieu of a paper copy, so long as the prescriber adheres to certain requirements.[53]

3. The Notice of Proposed Rulemaking and Eyeglass Rule Workshop

After the amended CLR final rule took effect, the Commission resumed its review of the Eyeglass Rule. Based on a review of comments received in response to the ANPR, a regulatory review of the CLR, and the Commission's enforcement experience, the Commission issued a notice of proposed rulemaking (''NPRM'') on January 3, 2023.[54] In the NPRM, the Commission proposed to: (1) require that prescribers obtain a signed confirmation after releasing an eyeglass prescription to a patient, and maintain each such confirmation for a period of not less than three years; (2) permit prescribers to comply with automatic prescription release via electronic delivery if the prescription is provided in a digital format that can be accessed, downloaded, and printed by the patient,

and if the prescriber obtains the patient's verifiable affirmative consent to the electronic delivery method; (3) clarify that the presentation of proof of insurance coverage shall be deemed to be a payment for the purpose of determining when a prescription must be provided; and (4) amend the term ''eye examination'' to ''refractive eye examination'' throughout the Rule.

In response to the NPRM, the Commission received 27 comments from various individuals and entities, including consumers, optometrists, ophthalmologists, opticians, trade associations, consumer advocates, and eyeglass sellers.[55] The Commission also announced it would hold a public workshop to consider: the proposed confirmation-of-prescription-release requirement for eyeglass prescriptions; consumers' and prescribers' experiences with the implementation of the similar requirement for contact lens prescriptions; other proposed changes to the Rule; and other issues raised in response to the NPRM.[56] The workshop notice invited interested parties to request to participate as a panelist or to file a comment.[57] Staff convened the workshop, titled ''A Clear Look at the Eyeglass Rule,'' with three panels and a total of 13 panelists in Washington, DC, on May 18, 2023, and the discussion was transcribed.[58] At the conclusion of the workshop, panelists, audience members, and the general public were invited to share additional views, data, and other information related to the NPRM and the subjects discussed, after which the Commission received an additional 20 comments, providing further perspectives from consumers, prescribers, opticians, trade associations, and retailers, as well as a U.S. Congressman.[59]

4. Overview of the Final Rule

The Commission now issues this final rule that largely adopts the amendments proposed in the NPRM, with some minor modifications based on public comments and other considerations, as discussed below. In issuing this final rule, the Commission has relied on an extensive record that includes comments received in response to the ANPR, the NPRM, and the workshop notice. The Commission also relies on the discussion at the May 2023 workshop, the Commission's experience enforcing the Eyeglass Rule and Contact Lens Rule, and the rulemaking record for the 2020 amendments to the CLR, to the extent that such record is pertinent to the Eyeglass Rule.[60] The Commission has also examined the current state of the marketplace, and the content of consumer complaints about prescriber practices. Further, the Commission remains cognizant of the lengthy regulatory history and evidentiary record pertaining to prescribers' failure to release prescriptions, and eyewear-specific market incentives (such as that many eye doctors sell the same items that they prescribe) that provided the initial impetus for both the Eyeglass Rule and the CLR.

Based on the entirety of the record, the Commission finds that prescribers' failure to 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[61]—remains prevalent, and tens of millions of Americans every year are not receiving their eyeglass prescriptions as required.[62] The Commission also finds that 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. The Commission further determines that the Rule's automatic-release requirement remains the best remedy for failure to release prescriptions, and that documentation of prescription release is necessary to better effectuate and enforce this remedy. Consequently, the Commission is amending the Rule to implement a confirmation-of-prescription-release requirement similar to that already in place under the amended CLR, albeit a simpler version.[63] Pursuant to these amendments, prescribers will be required to do one of the following:

(i) If a paper copy of the prescription was provided to the patient, request that the patient acknowledge receipt of the prescription by signing a separate statement on paper or in a digital format confirming receipt of the prescription; or

(ii) 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.

As with the CLR provision, this final rule provides sample language for the confirmation option, but also allows prescribers to craft their own confirmation wording if they so desire. As with the CLR's confirmation requirement, the requirement for eyeglass prescriptions would apply only to prescribers with a financial interest in the sale of eyeglasses.

The Commission believes that revising the automatic-release remedy to require a confirmation of prescription release will provide an educational benefit to consumers and prevent consumer harm. This amendment is necessary due to demonstrated failures of prescribers to comply with the automatic-release remedy, and to ensure the separation of eye examination and eyeglass dispensing, which engenders a competitive marketplace for eyeglasses. The Commission is sensitive to any additional burden that this rule change imposes. However, it finds that this amendment maximizes the benefits of comparison-shopping while imposing a relatively small cost. The potential benefit of increasing the number of patients in possession of their prescriptions is substantial: namely, increased flexibility and choice for consumers; increased competition among eyeglass sellers; 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.

The confirmation requirement also brings the prescription-release-related provisions of the Rule into congruence with those of the CLR, thereby reducing the confusion and complexity that arise for both consumers and prescribers from having inconsistent requirements for eyeglass and contact lens prescriptions. In addition, because the CLR already obligates ophthalmologists and optometrists to obtain a confirmation and maintain a record, their marginal cost associated with the confirmation requirement in the Eyeglass Rule should be extremely low. Prescribers in compliance with the CLR should already have in place forms, systems, and staff training for prescription release, and should only need to make minor adjustments for eyeglass prescriptions.

The Commission is also amending the Rule to permit prescribers to comply with automatic prescription release via electronic delivery in certain circumstances. In order to do so, the prescriber must identify the delivery method to be used—such as portal, text, or email—and the prescription must be provided in a format that can be accessed, downloaded, and printed by the patient. Further, a prescriber may only opt for digital delivery after obtaining the patient's verifiable affirmative consent, and must maintain evidence of that consent for a period of not less than three years. The Commission is also revising the Rule to clarify that presentation of proof of insurance coverage shall be deemed a payment for the purpose of determining when a prescription must be provided

under 16 CFR 456.2(a). Again, these revisions harmonize the Eyeglass Rule with the existing Contact Lens Rule, which should reduce confusion and complexity. And lastly, the Commission is further clarifying that the term ''eye examination'' in the Rule refers to a refractive eye exam, and is amending that term accordingly.

This final rule summarizes the public comments the Commission received, and explains why the Commission continues to believe that the Rule and its automatic-prescription-release provision are necessary. It also explains the Commission's rationale for adopting the amendments previously proposed in the NPRM, with some minor modifications.[64] Finally, this final rule sets forth the Commission's regulatory burden analyses under the Regulatory Flexibility and Paperwork Reduction Acts, as well as the regulatory text of the final rule.

5. The Eyeglass Marketplace

The retail vision care industry in the United States consists of several types of participants, namely ophthalmologists, optometrists, opticians, and eyewear retailers. The services provided by these different participants often overlap, and 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 college, four years of medical school, a year of general internship, and three years of specialized hospital residency training in ophthalmology. It is estimated that there are approximately 18,000 active ophthalmologists in the United States.[65] Many ophthalmologists, especially those who specialize in surgery or particular eye conditions, do not sell eyewear, although some do.

Optometrists are doctors of optometry. They have not completed medical school, but have instead completed four years of medical training in optometry school, typically following a four-year college degree. They are trained and licensed to examine eyes, diagnose refractive problems, prescribe and dispense eyeglasses and contact lenses, and detect eye disease.[66] 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 reports that in 2020 there were some 43,000 active optometrists in the United States.[67] While professional services—such as eye health and refraction examinations—generate significant revenue for optometrists, the majority of optometrists still derive a larger percentage of their income from product sales, including the sale of eyeglasses and contact lenses.[68] According to some estimates, product sales typically account for roughly 45 to 60% of optometrist revenue.[69]

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. According to one source, twenty-one States currently require opticians to obtain licenses,[70] 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 some form of apprenticeship or training. A 2020 estimate put the number of active opticians in the United States at approximately 73,000.[71] Opticians sometimes co-locate their optical dispensaries with examination offices of optometrists or ophthalmologists and, sometimes, although not always, share revenue from the sale of eyeglasses and contact lenses.

Eyewear retailers are companies and independent merchants that sell glasses. They often are 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 either an ophthalmologist, optometrist, optician, or optical retailer on site [72]), 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 Zenni Optical and *GlassesUSA.com*.

The overall retail eyeglass market continues to grow in both the number of eyeglass wearers as well as the number of eyeglasses purchased. It is currently estimated that approximately 165 million American adults regularly wear prescription eyeglasses, representing nearly two-thirds of the country's adult population,[73] and the overall market for eyeglass frames and lenses is estimated at $35.6 billion.[74] That represents an 18% increase in value from 2019.[75]

An industry report found that more than half of Americans surveyed between January 10 and March 19, 2023 had had an eye exam within the previous twelve months, and of those who had an eye exam in the previous three months and use eyeglasses, 50% purchased new eyewear.[76] While online eyeglass sales have increased significantly (in just the four years of 2019–2022, online sales of frames and lenses nearly doubled from $1.82 billion to $3.24 billion),[77] roughly four out of five eyeglass purchases still occur in person.[78] Furthermore, of those who have an eye exam and proceed to purchase eyeglasses, the vast majority purchase from their prescriber on the day of the exam.[79] This is often referred to as a prescriber's ''capture rate,'' [80] and remains relatively high for a variety of reasons, even though the average unit price for frames and lenses in 2022 was $360 from independent optical retailers and prescribers compared to just $183 from online eyewear sellers.[81] For many consumers, the convenience of being able to shop at the same location that they have their exam makes it worthwhile to buy glasses from their prescriber, even if they are more expensive. Many consumers also find it advantageous to try on glasses in person and have an expert tell them, based on their prescription and physical characteristics, the pros and cons of particular eyewear.[82] In-person optical dispensaries can also perform precise facial measurements to provide a more personalized fit.[83] Buying from one's prescriber can also make it simpler to have glasses adjusted post-purchase, if necessary.[84] As discussed *infra,* however, some consumers buy eyeglasses from their prescriber because they feel pressured or obligated to, or are unaware that they can take their prescription and shop elsewhere for glasses.

Final Rule Pertaining to the Automatic-Prescription-Release Provision

A. Separation of Examination and Dispensing

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 allows, 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 no ophthalmic goods were required.[85] Sections 456.2(b) and (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. Section 456.2(d) provides that it is an unfair act or practice for a prescriber to waive or disclaim prescriber liability for the accuracy of the eye examination or the accuracy of the ophthalmic goods and services dispensed by another seller.

These provisions, often referred to as the automatic-prescription-release requirement (also referred to as the required ''separation of examination and dispensing''),[86] were intended to make it clear that the purchase of eyeglasses is separate and distinct from the act of obtaining an eye exam, and to ensure consumers have possession of their ophthalmic prescriptions so they are able to ''price shop'' for eyeglasses.[87] Absent physical possession of their prescriptions, consumers do not have the ability—and in some cases, the knowledge—to buy eyeglasses wherever they want. Consequently, there is less comparison-shopping, and less incentive for eyeglass sellers to advertise or compete with each other on price or service.[88]

1. Comments and Evidence Regarding the Automatic-Prescription-Release Provision

In response to the Commission's NPRM, and during and after the Eyeglass Rule workshop, numerous commenters addressed the Rule's automatic-prescription-release provision, weighing in on whether (a) prescribers comply with the requirement and consumers receive their prescriptions, and (b) compliance is still necessary and beneficial for consumers.

a. Prescriber Compliance With Automatic Release, and Consumer Receipt of Their Prescriptions

Several commenters stated that even though the automatic-release provision has been in effect for decades, prescribers still do not adhere to this requirement, and thus consumers often do not receive a copy of their prescription. Longtime eyewear consumer and ER workshop panelist Felecia Neilly, for instance, recounted how she has visited various eye doctors at least 50 times over the course of her life, and yet has rarely been handed her prescription without having to request it.[89] ''It just always felt like there was a reluctance [on the part of the prescriber] in getting the complete information needed to fill the prescription, always,'' commented Neilly, adding that if the Rule has been in effect since the '70s, it should be automatic.[90] Neilly added that even when she did request her prescription, she did not always receive the complete copy, thus making it a challenge for her to purchase eyewear.[91]

Likewise, the National Association of Retail Optical Companies (''NAROC''),[92] a trade association comprised of retail optical companies with co-located eye care services (such as LensCrafters, Costco Optical, and Walmart Vision Center), submitted a comment stating, ''We have no evidence to contradict the [previous Commission] finding that prescribers' failure to automatically provide customers 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.'' [93] One Michigan optometrist, Dr. David Durkee, commented that ''the far majority of my colleagues do not engage in such practices [automatic release of prescriptions] out of fear of losing [retail] business.'' [94]

Other members of the ophthalmic community, on the other hand, typically felt that compliance with the automatic-prescription-release provision is routine and common practice. Workshop panelist Dr. Jeffrey Michaels, a Virginia optometrist, commented, ''I think that the automatic compliance with this [prescription release] is so ingrained in optometrists and ophthalmologists that it's just a normal part of their day.'' [95] He noted that in his optometric office, 100% of prescriptions are automatically uploaded to a patient portal ''the very second the prescription is finalized.'' [96] The American Academy of Ophthalmology (''AAO'') volunteered that ophthalmology practices ''have a tremendous track record of compliance with existing prescription release requirements,'' [97] and the Opticians Association of America (''OAA'') and American Optometric Association both noted that online eyeglass sales have been steadily increasing year over year, which they believe indicates that consumers have copies of their prescriptions.[98]

The American Optometric Association also pointed to the fact that, over the past five years, there had been fewer than fifty prescribers warned by the FTC for potential violations of the Eyeglass Rule (such as failure to release prescriptions).[99] The dearth of complaints was also emphasized by other optometrists, such as Dr. Michaels,[100] who said, ''Well, we heard that there were 30-some-odd letters [relating to complaints of non-compliance] out of 55,000 doctors who prescribe,'' and Dr. Scott Sanders, a Mississippi optometrist, who commented, ''The FTC is trying to fix something that is not broken . . . Prescriber compliance is 99.99999%.'' [101] Additionally, the American Optometric Association cited a consumer survey, performed at its behest by NERA Economic Consulting, which purportedly found that only 3 of 1072 eyeglass consumers polled mentioned a possible Eyeglass Rule automatic-release compliance issue, and this, according to the American Optometric Association, indicates that non-compliance is not prevalent.[102]

However, the NERA survey did not specifically address prescription-release compliance,[103] did not directly ask consumers whether they received their prescription from their prescriber, and did not ask consumers if they were aware of their right to their prescription.[104] Rather, the survey focused on where consumers purchased their eyeglasses and contact lenses, and why they purchased from that particular location. When consumers were asked to select the reasons that they purchased from that location, none of the 17 options offered included the availability or unavailability of their prescription (such as ''Because my prescriber didn't give me my prescription.''). The only way for survey respondents to reference prescription availability or unavailability was when asked open-ended questions such as ''In your own words, why did you purchase glasses from [the location that you did]?'' and ''Why did you ONLY consider purchasing glasses from [the location that you did]?'' In response to these questions, three consumers volunteered that they either thought they were required to buy from their doctor, or

that they bought from their doctor because the prescriber would not provide them with a copy of their prescription.[105] Since only three consumers mentioned the lack of prescription release, the American Optometric Association contends that noncompliance must not be an issue.[106]

Though the NERA survey provides some insights discussed later in this document, the Commission does not find the survey to be probative as to whether prescribers are releasing prescriptions (either automatically or on request). The fact that only three consumers [107] proactively mentioned that prescribers had not provided them with their prescriptions could, perhaps, suggest that prescribers typically comply, but cannot be accorded significant evidentiary weight since consumers were not actually asked whether they received their prescriptions.

The Commission also notes, as it has repeatedly in the past, that the raw number of consumer complaints about prescriber non-compliance is an unreliable barometer of prescriber compliance. As discussed in some detail during the Contact Lens Rule review, the Commission's experience has shown that the vast majority of injured or impacted consumers do not typically register complaints with the government, and even fewer are likely to submit a complaint about an FTC rule violation such as a prescriber's failure to release their prescription.[108] This is especially true when—as will be discussed later in this final rule—evidence shows that many consumers remain unaware that they have an unconditional right to their prescription and should be receiving them automatically after each refractive exam. As workshop panelist Neilly commented, the lack of consumer complaints may correlate to the lack of knowledge about the prescription-release requirement ''because people don't even know there's an Eyeglass Rule.'' [109] And even if consumers are aware that they have a right to their prescription and should have received it, they might not know to whom to complain in instances when it wasn't given to them.

Apart from the NERA survey, none of the commenters to the NPRM or Eyeglass Rule workshop supplied new or updated empirical evidence. The extensive evidentiary record, however, includes two previously submitted surveys that shed light on the percentage of patients that do or do not receive their prescriptions. A survey conducted on behalf of Warby Parker by the polling firm SurveyMonkey reported that, of consumers who had purchased eyeglasses within the last three years, 47% of those who saw optometrists and 31% of those who visited ophthalmologists were not automatically provided with a physical copy of their eyeglass prescription.[110] The survey also found that 14% of consumers had to pay their prescriber for a copy of their prescription when they requested a copy at a later time.[111]

Another survey—conducted on behalf of 1–800 CONTACTS by the polling firm Survey Sampling International (''SSI'')—found that only 34% of eyeglass wearers automatically received their prescriptions on the day of their office visit, with another 19% receiving it during their visit, but only after asking for it.[112] According to the SSI survey, some consumers were able to obtain their prescription at a later point by returning to their prescriber's office, but 39% of consumers never received their prescription at all.[113]

It is important to note that these surveys reveal more than simply that many prescribers fail to always comply with the automatic-release requirement. The surveys reveal that, even if prescribers will provide prescriptions *when asked,* a significant percentage of consumers leave their prescriber's office without their prescriptions. Which means that, for the next year or two (until their next eye exam), those consumers might be unable to shop for eyeglasses at an alternative location without having to contact their prescriber and ask for their prescription (and possibly have to pay for it). Although it is possible for other eyeglass sellers to call prescribers' offices and request patient prescriptions, this can lead to delays, and—in sharp contrast to the Contact Lens Rule—there is no legal requirement under the Eyeglass Rule that prescribers comply with requests to verify patient eyeglass prescriptions to third-party sellers.

The two surveys cited herein have been criticized by optometrists and the American Optometric Association, which contend the Commission should disregard their results because the surveys were submitted by retail competitors with a financial stake in the outcome of the rulemaking,[114] and were submitted as part of the FTC's Contact Lens Rule review, and the markets and patient experiences for eyeglasses and contact lenses are not the same.[115] The American Optometric Association cited to NERA's survey and comment for the premise that ''Commission conclusions and decisions regarding regulation in the contact lenses market cannot be presumed to apply to the eyeglasses market.'' [116] As evidence of this dissimilarity, AOA has pointed to the NERA survey finding that eyeglass users are more likely than contact lens users to buy their corrective eyewear from someone other than their prescriber.[117] AOA also noted that because contact lens fittings are not always complete in office due to patients taking home trial lenses to test, surveys of contact lens users may produce imperfect results in that consumers may report that they didn't receive their prescriptions at the end of their exam when, in fact, their contact lens fittings hadn't been finalized and so they weren't actually entitled to receive their prescriptions at that point.[118]

With respect to AOA's first argument, the Commission acknowledges that both Warby Parker and 1–800 CONTACTS have a financial interest in the outcome of the Rulemaking. The Commission recognizes, however, that nearly all commenters have some form of interest in the outcome. And thus, as a general practice, the Commission does not simply disregard data or opinions submitted by interested parties. Rather, the Commission takes into account the financial interests of submitting parties, but also, when possible, examines the underlying data and methodology submitted to gauge a survey's usefulness, and considers factors such as how many people are queried, how the questions are phrased, and whether the surveys are conducted in-house (by the interested parties themselves) or by independent and established third-party polling firms. Lastly, the Commission recognizes that all surveys are likely to have some methodological limitations, and thus the Commission will often decide not to treat any single survey as controlling or dispositive. The Commission is also aware, however, that multiple surveys conducted by different sources at different times with similar results tend to bolster the credibility of each individual survey.[119] In this case, the surveys submitted by Warby Parker and 1–800 CONTACTS are not flawless or immune to criticism, but were performed by reputable third-party polling firms and appear sufficiently reliable based on an examination of their questions and methodology.

As for AOA's assertion that the two surveys were submitted during the Contact Lens Rule review and thus are not relevant to this Eyeglass Rule review, the Commission cannot concur. The contention that the SurveyMonkey survey was submitted during the Contact Lens Rule review is incorrect. While the Survey Monkey data was referenced during the Contact Lens Rule review, it was submitted in response to

the Commission's Eyeglass Rule Advance Notice of Proposed Rulemaking in 2015 and was a survey of eyeglass wearers.[120] As for the SSI survey, that was indeed included as part of a submission during the Contact Lens Rule review, but that particular survey polled *both* contact lens users and eyeglass users about their experiences with prescription release, and distinguished between the two in its results. The SSI results cited above—showing that approximately only 34% of eyeglass wearers automatically received their prescriptions following their refractive eye exam, and 39% did not receive their prescription at all—are results *solely* of eyeglass users' experiences.[121] Any impact or effect caused by a dissimilarity in eyeglass and contact lens markets or experiences would not apply.[122] Thus, criticism that these surveys do not reflect the appropriate target group or take into account differences between eyeglass and contact lens users is misdirected, and these surveys merit the Commission's full consideration.

Moreover, the Commission cannot agree that other surveys detailing how contact lens users have not received their prescriptions do not have relevance in the context of the Eyeglass Rule. As noted above, there are, admittedly, differences in the examination and prescription processes for eyeglasses and contact lenses,[123] but the mandatory prescription-release requirements are similar, and there is little evidence to indicate that prescribers release eyeglass prescriptions in dramatically different numbers than they release contact lens prescriptions. And while the NERA survey indicates that contact lens users are less likely than eyeglass wearers to purchase from someone other than their prescriber, this has little or no bearing on whether consumers are receiving their prescriptions from their prescriber (although it may have some bearing on whether automatic release is necessary or beneficial, as discussed below).

The Commission therefore views the five additional consumer surveys submitted and considered during the CLR review—which found that between 21 and 34% of contact lens users did not receive their prescriptions when they were supposed to—as additional indications that prescriber compliance with prescription release, and overall consumer receipt of their prescriptions (whether contact lens prescription or eyeglass prescription), is sub-optimal.[124]

Furthermore, the Commission notes, as it did in the CLR final rule, that despite multiple opportunities and requests for comment since 2015, the Commission has yet to locate or receive any reliable consumer-survey data rebutting or contradicting the prescription-release data in the record for either contact lens users or eyeglass wearers, or establishing, other than anecdotally, that consumers consistently receive their prescriptions from prescribers as they are supposed to under the applicable FTC rule.[125] Based on the evidence in the record, it is thus the conclusion of the Commission that tens of millions of American consumers in need of corrective vision wear are not receiving their eyeglass prescriptions after visiting their prescriber each year.[126]

b. Whether the Automatic-Release Provision is Still Necessary and Beneficial for Consumers

Having determined that prescriber compliance with the Rule's automatic-release provision is deficient, and that many eyeglass consumers do not receive their prescriptions, the Commission next considers the impact of this deficiency, and whether such failure remains an unfair act or practice in need of remedial action, as originally determined by the FTC when it formulated the Rule.[127] Again, opinions on the need for, and benefit from, automatic prescription release, varied significantly in the comments received by the Commission. NAROC, for instance, opined that the automatic-release requirement—when complied with—provides a substantial benefit to consumers as it enables comparative shopping, and added there is ''no evidence to support a conclusion that the automatic release provision is no longer needed; to the contrary, the substantial expansion of consumer choice in recent years is strong evidence that this requirement has helped consumers and that it is more necessary than ever.'' [128] In a subsequent comment, the organization added, ''There is widespread agreement that the Commission should continue the 'automatic-prescription-release requirement' for eyeglasses,'' but evidence demonstrates that not all consumers are aware they should receive their prescription automatically, and some prescribers are not providing it.[129] Wallace Lovejoy from NAROC opined during the workshop that, while some people have their mind made up before they go to the eye doctor, and want to get an exam and buy glasses at the same time and place, ''there's a significant number of people who get an eye exam and wait to shop and go somewhere else. It's useful to have the prescription released and I would agree that the automatic release seems to make the most sense.'' [130]

Some other commenters endorsed this view. 1–800 CONTACTS, for example, stated, ''automatic prescription release is critical to promoting consumer choice and competition in the market for prescription eyewear,'' and ''prescribers are unlikely to comply with their automatic release obligations absent a credible threat of enforcement and fines. Prescribers have a strong financial incentive to withhold a prescription to discourage comparison shopping and pressure patients to purchase lenses inhouse.'' [131] One anonymous commenter submitted, ''Being able to have a prescription in your hands as soon as your examination is done would be very beneficial to a lot of people for many reasons. This would allow people to shop for different resources for their lenses and find the best price for them. It shouldn't be a hassle for someone to get their prescription . . .'' [132] Likewise, Sara Brown, from the advocacy organization Prevent Blindness, stated during the workshop, ''I think not having [automatic release] would make a major impact on patient access.'' [133] She noted that millions of Americans have difficulty affording eyewear, and not having information that makes it easier for them to comparison-shop would be detrimental.[134]

On the other hand, some commenters felt that, irrespective of whether prescribers automatically release prescriptions, prescribers no longer withhold prescriptions if directly asked for them. Dr. Arlan Aceto, a Connecticut Professor of Ophthalmic Design and Dispensing, for example, said during the workshop that he and his optician colleagues have not had a problem obtaining prescriptions from prescribers in instances where the patients failed to bring them,[135] and panelist Dr. Artis Beatty, a North Carolina optometrist, commented that oftentimes patients are issued a prescription but fail to have it on hand when they need it.[136] These comments suggest there may be less need for, and consequently less benefit from, the automatic-release requirement.

The most extensive criticism of the automatic-release requirement came from workshop panelist and NERA consultant Dr. Andrew Stivers,[137] who submitted a survey and lengthy comment that challenged the underlying basis for the requirement, noting, ''It's not just how much compliance, it's how impactful that compliance or lack of compliance is on consumers.'' [138] According to Dr. Stivers, the relevant issue is whether, and how much, consumers have their eyeglass-shopping options curtailed by failure of

prescribers to automatically provide patients with their prescriptions, since some consumers would not have shopped elsewhere even if they had received their prescriptions, and some consumers might have been offered their prescription and declined.[139]

Dr. Stivers argued that the Rule's automatic-release provision was meant to address a lack of competition resulting from market conditions that do not exist in today's ''information rich, dynamic market,'' and thus the Commission should reexamine whether automatic release still benefits consumers in light of two fundamental changes that have occurred in the market.[140] First, said Dr. Stivers, mass merchandisers and wholesale clubs have ''transformed'' the eyeglass shopping experience, and second, internet search and shopping has created a new, competitive channel for eyewear.[141] The original rule's finding of unfairness, according to Dr. Stivers, rested on a context of advertising restrictions [of eyeglass sellers], State restraints on trade, limited shopping options for consumers, and overt prescription-withholding behavior by prescribers, that rarely exists today.[142] Therefore, he contended, the Commission's ''determination of unfairness from 40 years ago cannot be presumed to apply today and thus there is no rationale or basis for new regulation in the prescription eyeglass market.'' [143] Furthermore, Dr. Stivers explained, ''Today, consumers can choose to shop before getting an exam, which increases incentives to provide information and increases competition in ways that the Commission of 1978 could not imagine,'' [144] and this change has made automatic release less likely to generate substantial benefit. And absent such benefits, per Dr. Stivers, lack of compliance with automatic release cannot be the basis for a determination of unfairness, or the proposed changes to the Rule.[145]

As evidence of the altered market and changed consumer behavior, both Dr. Stivers and the American Optometric Association pointed to the NERA survey, which found, among other things: that consumers have numerous options for eyeglass purchases; that one in three eyeglass purchasers consider alternatives to where they ultimately purchase; that consumers purchase glasses from alternative channels such as retail chains and online stores more than 50% of the time; that consumers choose purchasing locations for a variety of reasons (including price, service, familiarity, location), with convenience valued over all others; and that eyeglass purchasers are more likely than contact lens users to know about and consider alternative purchasing channels.[146] According to the American Optometric Association, these results demonstrate that consumers are aware of, and utilize, their eyeglass-purchasing options, and that there is a ''well-functioning and competitive market for eyeglasses,[147] thus calling into question the ''underlying premise that more must be done to encourage competition and choice in the eyeglass market.'' [148] The AOA further quoted Dr. Stivers' NERA report for the premise that the survey results ''do not support or uncover any systemic market failures requiring additional rulemaking that would benefit consumers.'' [149]

2. Analysis of Evidence Regarding Failure To Release Prescriptions

Having considered the evidence in the record—including the written submissions and workshop comments, empirical surveys of prescription-release and consumer knowledge, ongoing and historical patterns of consumer complaints and anecdotal reports, and other relevant evidence submitted during the CLR review (and the Commission's determinations in that regard), along with the industry's long-documented history of failing to release prescriptions in order to capture consumer eyewear purchases in-house—in context of the intent, purpose, and history of the Eyeglass Rule, the Commission finds that, regardless of the increased information and availability of purchasing alternatives in today's eyeglass marketplace, it remains an unfair act or practice for prescribers to fail to release a prescription to consumers. The practice denies consumers the ability to effectively use the information available, and continues to result in substantial economic loss and lost opportunity costs due to an impaired ability to comparison-shop for eyeglasses. The Commission finds that such conduct remains pervasive, is likely to cause consumers substantial injury, is not outweighed by countervailing benefits that flow from such conduct, and cannot reasonably be avoided by a substantial number of consumers.

The Commission does not dispute that mass merchandisers, wholesale clubs, and internet search and shopping have dramatically altered the overall retail landscape for eyeglass shopping. But these changes relate primarily to aspects of eyeglass shopping that occur *once a consumer already has a prescription in hand.* The initial experience of having an eye exam and obtaining a prescription remains much the same as it was when the Rule was created in that a consumer still has to be examined by an optometrist or ophthalmologist in order to obtain a prescription with which to buy eyeglasses. While Dr. Stivers has suggested that consumer emphasis on convenience when deciding where to buy glasses suggests they ''likely consider both where to get an exam and where to shop for glasses ahead of time for an efficient shopping experience,'' [150] the NERA survey does not reveal to what extent this pre-exam shopping occurs, and Dr. Stivers acknowledged that he was unaware of any survey evidence establishing that many consumers comparison-shop *before* choosing their eyecare provider.[151] The Commission is not aware of any empirical evidence showing whether pre-exam shopping is prevalent, nor—even if it is—whether that means consumers no longer want or need a copy of their prescriptions. It also would not aid consumers who are hesitant to ask for their prescription, or feel pressured to buy glasses from their prescriber—whom they may view as a respected medical ''authority figure'' [152]—even if consumers' pre-exam intention was to take their prescription and buy glasses elsewhere. Furthermore, even if consumers decide pre-examination that they want to buy glasses from their prescriber, and thus do not need a copy of their prescription, they could still be harmed by a prescriber's failure to release their prescription if, at a later date, those consumers want to purchase additional or replacement eyeglasses, and lack a copy of their prescription. In addition, as Dr. Michaels noted during the workshop, many consumers go in for an eye exam every year without any intention of buying glasses,[153] only to learn during their exam that they now need vision correction, or that their vision correction has changed.

Dr. Stivers is correct in that not all consumers necessarily benefit from receiving a copy of their prescription. Some consumers prefer buying glasses from their prescriber for convenience, or trust the expertise of their prescriber's staff to help fit them with the most appropriate eyewear. Some consumers simply favor the prescriber's frame options. But in trying to calculate how much consumer eyeglass-shopping options are, or are not, curtailed by the failure to receive their prescriptions, the Commission faces a dilemma in that consumer decisions and preferences with respect to buying eyeglasses are impacted by the fact that so many consumers are not given a copy of their

prescription. Widespread lack of automatic prescription-release renders it difficult, if not impossible, to determine what percentage of consumers opted to buy glasses from their prescriber because they favored the prescriber's convenience, selection, and expertise, and what percentage opted to buy from their prescriber because they did not have a copy of their prescription, did not feel comfortable asking for one, or did not even know that they could. In sum, it is unlikely that consumers' current conduct and preferences regarding where they purchase eyeglasses can fully establish how much is or is not to be gained from improving compliance with the Rule's automatic-prescription-release requirement because current consumer conduct and preferences are colored (and perhaps unfairly influenced) by current prescriber non-compliance with automatic prescription release.[154]

Ultimately, it is the Commission's view that, regardless of the widespread availability of information and alternative opportunities to buy eyeglasses, not possessing a prescription continues to impede consumer options and comparison-shopping for eyeglasses. By many accounts, the Eyeglass Rule, and the removal of State restrictions, have played a major role in significantly altering and improving the information and alternatives available to eyeglass consumers.[155] But possession of the prescription remains the key that unlocks the door to this altered and improved marketplace. As workshop panelist Lovejoy commented, ''[t]he ability to advertise doesn't matter if you don't get a copy of your prescription.'' [156] The Commission noted this when promulgating the Eyeglass I Rule, declaring that the injury arising from failure to release prescriptions is clear in that consumers are denied ''the ability to effectively use available information, and inhibit the functioning of the competitive market model,'' and therefore, the failure to release prescriptions immediately after the eye examination is completed is, in and of itself, an unfair act or practice.[157] This holds true irrespective of other changes and improvements in the eyeglass marketplace.

Furthermore, it remains evident that many consumers are still not fully knowledgeable about their unconditional right to their prescriptions, and thus their ability to avoid or self-remedy harm arising from not possessing their prescriptions. While prescribers have often asserted that consumers are well-aware of their purchasing options,[158] the Commission continues to receive communications evidencing that some consumers do not even realize they are entitled to their prescriptions.[159] As workshop panelist Brown noted, ''there was a question that was [asked] earlier about why don't patients ask for this information? Because they don't know.'' [160]

Indeed, some surveys have found that consumer awareness of prescription rights remains less than ideal. According to a 2015 survey—performed on behalf of 1–800 CONTACTS—49% of prescription eyeglass wearers are not aware that they have a right to receive their eyeglass prescription, and 51% are not aware that their eye exam provider cannot charge for their eyeglass prescription.[161] Multiple consumer surveys reviewed during the Contact Lens Rule review reinforce this by showing that a high percentage of contact lens users (46 to 60%, according to submitted data) still do not realize they are entitled to receive their contact lens prescription,[162] and it is probable that many of these consumers are also unaware they are entitled to their eyeglass prescription. The percentages of consumers unaware of their rights have been found to be even higher for traditionally underserved groups such as African Americans and Hispanics,[163] and due to less English language proficiency, non-native speakers may also be less likely to speak up and request their prescription—even if they know they can—if it is not automatically provided by their prescriber. There are also significant numbers of consumers each year who are new to the need for corrective eyewear, and thus have little experience with eye examinations, including whether they should receive a copy of their prescription. Therefore, the Commission concludes that while the NERA survey may suggest that some percentage of consumers is now aware of their option to obtain eyeglasses from a source other than their prescriber, the number of consumers fully informed of their prescription rights, and of their ability to take their prescription and shop elsewhere, remains sub-optimal.

Furthermore, as noted previously, the Commission is also aware that some consumers know they have the right to their prescription but may feel pressure to purchase from their prescriber, or feel uncomfortable asking for their prescriptions since it signals to the prescriber that they plan to purchase eyewear at a different location.[164] Consumers often like and respect their prescribers, and are hesitant to do something that might be perceived as disloyal.[165] Other consumers may be reluctant to acknowledge to their prescriber that they are cost-conscious and have concerns about their ability to afford eyewear at the price charged by their prescriber.[166]

After considering all of the evidence, the Commission concludes that when prescribers do not release prescriptions, it still harms consumers and puts them at a disadvantage in the marketplace, and thus continues to require remedial regulation.

B. The Remedy for Failure To Release Prescriptions Remains the Automatic-Release Requirement

In fashioning a remedy for an unfair act or practice, the Commission has wide latitude, and need only show a ''reasonable relation'' between the unfair act or practice and the remedy.[167] When, in the past, the Commission has considered how to remedy failure to release, it evaluated a variety of options, including, among other things, release-upon-request, offer-to-release, and increased signage and consumer education, and yet the Commission repeatedly determined that the most effective remedy is to require automatic release of prescriptions regardless of whether a consumer requests one following an examination. The Commission still finds this to be true and concludes that automatic release as a remedial measure continues to have a reasonable relationship to the unfair act or practice of withholding prescriptions. The Commission continues to find that automatic release remains the optimal remedy for prescribers' failure to release prescriptions because absent the requirement: (1) even more doctors would not always provide patients with their prescriptions, as demonstrated by surveys indicating that they often do not presently, even though required to do so; (2) large numbers of patients would not ask for their prescriptions due to a lack of awareness of their unconditional right to their prescription; (3) some patients would be reluctant to ask for their prescriptions (particularly underserved groups); and (4) release-upon-request would inappropriately place the burden on the consumer. Release-upon-request would also be difficult for the Commission to enforce because, absent documentary evidence, it would likely turn into a debate as to whether a patient did or did not ask for their prescription.

While the Commission concludes that automatic prescription release remains the best remedy for the unfair practice of failure to release, it is also evident from the record that the remedy has not fulfilled its potential. The remedy has been in effect for over forty years, and yet a significant number of consumers are still not receiving their

prescriptions. The Commission therefore turns next to examine ways to improve the automatic-release remedy via amendments and clarifications to the Rule.

C. Commission Determination To Update the Rule To Clarify Requirements for Prescription Release

One prescription-release issue that is periodically brought to the attention of the Commission relates to the timing of the Rule's required automatic prescription release—*i.e.,* at what point that release must occur during a patient's office visit to their prescriber. The Rule, as presently written, states that it must occur ''immediately after'' the eye examination is completed, but that a prescriber may withhold the prescription until the patient has paid for the examination if the prescriber also requires immediate payment from patients for whom the examination revealed that no ophthalmic goods were required.[168] The words ''immediately after,'' however, have not previously been discussed or clarified in detail, and some non-prescribing eyewear sellers have raised concerns that prescribers who also sell eyewear have a tendency to lead patients into the prescriber-owned optical dispensaries and offer to sell them eyeglasses immediately following an examination and *before* providing their patients with their prescriptions.[169] Some prescribers and optometric consultants even recommend such an approach as a way of increasing customer ''capture rate.'' [170] When this occurs, the prescription copy is only released to the patient after they have already shopped for eyeglasses, when they are checking out and paying their total bill (a bill that would include the cost of the examination, as well as the cost for new glasses).

As noted during the Eyeglass Rule workshop, the Commission believes that prescribers holding onto a prescription until after they have already made an eyeglass sale runs contrary to both the letter and purpose of the Rule.[171] The letter of the Rule is clear. The prescriber must provide the prescription ''immediately after the eye examination is completed.'' [172] The policy of the Rule, as it relates to the timing of prescription release, is also clear in several ways. First, the regulatory history makes evident that two of the foundational purposes of the Rule have been to (a) separate the eye examination from the purchase of eyeglasses, and (b) ensure that consumers have possession of their ophthalmic prescriptions so they are able to comparison-shop for glasses.[173] The singular fact that eyeglass prescribers sell what they prescribe [174] (a practice that some members of Congress have called an ''inherent conflict of interest'') [175] already blurs the distinction between eye examination and the purchase of eyeglasses, and when a prescriber offers to sell consumers glasses before releasing their prescriptions, it blurs that distinction even further.

Additionally, as noted at the time the Commission first created the Rule, the prescription itself is ''the means by which consumers can comparison shop.'' [176] Absent a prescription in hand, (whether that be physically in hand, or digitally uploaded to a patient portal and readily accessible to the consumer), consumers might not even realize they have an option to comparison-shop for their glasses. They may be confused, or misled, into thinking that the examination and purchase of eyeglasses are part of a unitary, or ''total vision care'' process, a once-common practice in the ophthalmic community in which the sale of eyeglasses was tied to the examination, and by scheduling an eye exam, a patient was essentially committing to purchase eyewear (if they needed it) from the same location at which they were examined.[177]

While there is nothing inherently wrong with consumers buying eyewear from the prescriber who conducted their refractive examination, and there may be benefits to it,[178] the Eyeglass Rule was created because the Commission determined it was an unfair practice when consumers did not at least have the option to buy glasses from someone other than their prescriber. The Commission believes it is problematic if patients are confused about whether they have, or do not have, the option to separate the examination process from the commercial purchase of eyeglasses. And even if patients recognize that by coming for an examination they are not committing to buy glasses from their prescriber, they may feel pressure to do so, a pressure heightened by the fact that until they possess a copy of their prescription, they cannot shop at any other locations.

Lastly, the practice of not providing prescriptions until after the patient has selected eyeglasses can lead consumers to believe that they are receiving their prescription because it comes with the eyeglasses, or to believe that what they are paying for is their prescription copy, when, in fact, they are paying for their examination, and the prescription copy is free per the Rule. The Commission periodically receives complaints from consumers who believe they were charged for their prescription when, in actuality, consumers were charged for their examination, but the confusion arose because the prescriptions were only handed over after the consumers paid.[179]

Ultimately, of course, the consumer is free to buy eyeglasses from their prescriber. Many consumers prefer to do so,[180] and the Commission has no interest in preventing this. But to fully realize the intent and purpose of the Rule, consumers must have the unfettered option to buy from wherever they choose, and must not be confused or misled about their unconditional prescription rights, and whether their examination is connected to the purchase of glasses. To achieve this, consumers must have the prescription in their possession—whether physically or digitally—as soon as the prescription is finalized and before they are offered eyeglasses for sale.

For this reason, the Commission is revising § 456.2 to clarify that the prescription must be provided after the refractive eye examination is completed ''and before offering to sell the patient ophthalmic goods.'' This does not mean that a patient is not permitted to walk through a prescriber's eyeglass dispensary, or browse available eyeglass frames, before receiving a copy of their prescription. Nor does it cancel the Rule provision that a prescriber may make consumers pay for their exam before releasing their prescriptions, so long as that prescriber would have required immediate payment from the patient had the examination revealed that no ophthalmic goods were required.[181] But it does mean that if a prescriber (or the prescriber's staff) is ready and willing to sell that patient eyeglasses, the prescriber must release a copy of the prescription to the patient before moving forward with any aspect of the sale. If the prescription is released electronically (with the patient's consent), it must be uploaded to a patient portal or transmitted to the patient via email or text, and thus fully accessible to the patient before that patient is offered an opportunity to purchase eyewear. It also means that if the prescriber makes a medical determination to not write and release a prescription to a patient,[182] or withholds a prescription pending payment by the patient for the examination, the prescriber may not offer to sell that patient eyeglasses at that time.[183] The prescriber may only offer to sell the patient eyeglasses after the prescription is released.[184]

Furthermore, per the discussion above regarding automatic prescription release, the Commission still concludes—as it concluded multiple

times in the past—that the burden of ensuring prescriptions are released must rest on the prescriber and not the patient.[185] And thus automatic release must occur regardless of whether or not the prescription is requested by the patient. This has always been the intent of the Rule—and is already reflected in the existing requirement that the patient's prescription must be provided ''immediately'' after the examination—but, unlike with the Contact Lens Rule, it has never been specifically stated in the Rule text. To ensure that is clear, and to bring the Eyeglass Rule prescription-release requirement into concordance with that of the Contact Lens Rule, thereby simplifying compliance, the Commission is further revising § 456.2 to clarify that the prescription must be provided ''whether or not the prescription is requested by the patient.'' This does not mean that a prescriber must force the prescription on a patient who does not want a copy. The patient is always free to refuse a copy, in which case the prescriber should merely note that in their files. But prescribers and their staff must at least attempt to give the patient a copy of the prescription, rather than merely offer to provide a copy, or just wait and see if the patient asks for it.

Neither of these clarifications alter the burden on prescribers, they merely make clearer what is already required by the Rule, and what should already be occurring in practice.

III. Final Rule Pertaining to Affirmative Consent to Digital Delivery of Eyeglass Prescriptions

A. Digital Delivery Option in the NPRM and the Basis for Such Amendment

As discussed above, § 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. The Rule, as currently codified, does not expressly permit electronic delivery of prescriptions as a means for automatic prescription release. In the NPRM, the Commission considered technological advances, such as the proliferation of patient portals, along with prescriber-to-patient communication via email or text, that could facilitate the transmission of the prescription to the patient once the eye exam is completed, and thereby enhance prescription portability.[186] The Commission opined that permitting electronic delivery in certain circumstances could provide benefits to consumers, and proposed amending the Rule to permit such delivery after the prescriber obtains the patient's verifiable affirmative consent.[187]

To ensure that patients are able to make an informed choice about whether to agree to electronic delivery, the proposal required that the prescriber identify the particular delivery method to be used, such as portal, text, or email, and the prescription would need to be provided in a digital format that can be accessed, downloaded, and printed by the patient.[188] 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. To aid Commission enforcement efforts to monitor compliance with the Rule, the Commission proposed that prescribers be required to keep a record or evidence of a patient's affirmative consent for a period of not less than three years.[189]

This proposed amendment to the Eyeglass Rule mirrored a change made to the CLR in 2020, allowing prescribers to satisfy the CLR's automatic-release requirement by providing the patient with a digital copy of his or her contact lens prescription 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.[190] In the CLR SNPRM, the Commission noted that providing patients with an electronic copy of their prescriptions 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.[191]

B. Comments on the NPRM and Discussion at the Workshop Regarding the Proposal To Permit Digital Delivery of the Eyeglass Prescription With Patient's Affirmative Consent

In addition to seeking general comments on the benefits and burdens of this proposed change, the Commission invited public comment on whether prescribers would choose to satisfy the automatic-prescription-release requirement through electronic delivery if permitted by the Rule, and whether patient portals, emails, or text messages would be feasible methods for the provision of digital prescription copies. The Commission also asked what other technologies are available that could be implemented to improve prescription portability, and thereby increase benefits and decrease burdens related to prescription release.

1. Comments About the Benefits and Burdens of the Proposed Affirmative Consent to Digital Delivery Provision

The Commission received generally positive feedback on the proposed digital delivery provision, with commenters noting that it would allow the Rule to keep pace with technology and it would help patients understand their rights under the Rule.[192] The AOA opined that this would be a ''commonsense update'' that would ''ensure [ ] that the FTC's regulatory language is keeping pace with updates in technology.''[193] NAROC suggested that the ''impact of allowing a prescriber to release the [prescription] in digital form will be to increase patient understanding of their rights, because every instance of receipt of a digital copy of the prescription will require affirmative consent to such delivery and will help build an expectation on the part of consumers that they are entitled to the prescription.''[194]

Other commenters who objected generally to the burden of other proposed changes, including the proposed confirmation requirement, pointed to the widespread transition to electronic health records (''EHRs'') or electronic medical records (''EMRs'') and argued in favor of prescription availability via a portal as being wholly sufficient to address the FTC's concerns about prescription release, and ensure patient access to their prescription.[195] Another commenter, an ophthalmic technician, expressed concerns over the added recordkeeping burden from the proposed confirmation requirement, noting that their practice already has a record of the prescription on file for the patient and that most EHRs track when prescriptions are printed out.[196]

Although having a prescription available on file upon request (either in a paper record or accessible through an online portal) would not satisfy the automatic-prescription-release requirement, the Commission considered the proliferation of patient portals and EHR systems in the NPRM, and discussed both the potential benefits available to consumers, prescribers, and sellers through the use of such systems, as well as the possible drawbacks. On the benefit side, a patient using a portal 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.[197] The use of health information

technologies, such as patient portals, could also reduce costs for prescribers, patients, 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, it is likely that patient portals do 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.[198]

The Commission is aware, however, of potential drawbacks in relying on electronic records exclusively for prescription delivery. In the recent CLR rulemaking, commenters expressed concerns that: (1) online portals are not widely used; (2) patients may not always be aware of the portal or may have difficulty accessing or printing documents online; and (3) some prescribers and patients prefer paper copies.[199]

Recent data shows that the number of prescribers offering patients access to their health information through an EHR system or patient portal has increased significantly. A survey from 2022 found that nearly 3 out of 5 U.S. adults reported they were offered and accessed their online medical record or patient portal, which was a 50% increase since 2020.[200] Patients also increased their use of apps to access online medical records, and patients using apps to view their online medical records accessed them more frequently than those who used only a web-based method.[201] Available information suggests, however, that disparities still exist in the availability and use of patient portals among some populations, including older patients.[202] A variety of factors may influence the limited portal use in such populations, including lack of access to technology and personal preference, and some groups (including Black and Hispanic individuals) may be less likely to report being offered access to a portal in the first place, suggesting a need for improvement in provider communication and clinic practices.[203] In addition, of those patients who access their online medical records through an app or web-based patient portal, relatively low numbers are downloading and transmitting their health information, which ''suggests a need for further education of both individuals and providers on these features,'' according to the Office of the National Coordinator for Health Information Technology.[204]

2. Comments in Favor of Allowing Prescribers to Choose Whether To Offer Digital Delivery of Prescriptions

A number of commenters supported making the decision to offer digital prescription delivery—either at all or using particular delivery methods—a voluntary one on the part of prescribers.[205] For example, NAROC approved of not requiring prescribers to provide prescriptions electronically, but noted that some prescribers may already be complying with the CLR prescription-release requirement through digital prescription delivery and, for these prescribers, permitting compliance with the Eyeglass Rule in the same manner would create efficiencies for prescribers' offices.[206] Some commenters also suggested that compliance with the automatic-release requirement is made easier by the digital delivery option due to the ease of emailing either the prescription itself or a link to a portal on which the prescription is available.[207]

One anonymous commenter questioned whether portals would need to be configured to require a patient signature whenever a patient accesses the portal to print a prescription.[208] Workshop panelist Dr. Michael Repka, Medical Director for Governmental Affairs at the AAO, described an intricate process his office undertakes to attempt to obtain a signature of prescription-receipt from a patient who accesses their contact lens prescription via a portal.[209] The Commission, however, notes that this represents a misunderstanding of the CLR's digital-prescription-delivery provision, which specifically removes the signature-requirement when prescriptions are digitally delivered, and likewise, confirmation signatures would not be required when prescriptions are delivered digitally under the amended Eyeglass Rule. Using a digital delivery method to comply with § 456.2 would relieve the prescriber of having to collect a signature from the patient confirming their receipt of the prescription.[210] Under the new § 456.4(a)(1)(ii), prescribers using a digital delivery method would not need to request that the patient sign a separate statement confirming receipt of the prescription.[211] Instead, prescribers would need merely to retain evidence that the prescription was sent, received, or made accessible, downloadable, and printable, which commenters have acknowledged EHRs generally are configured to do.[212] Similarly, an emailed or texted prescription should create its own record of transmission, and therefore involve minimal burden to the prescriber.

Other commenters shared that the existence of electronic health records in a medical practice does not automatically result in a patient having access to their prescription on a portal,[213] and that some prescribers may be using simplified websites to provide prescription delivery without giving a patient full access to all of their exam information, in order to make access simpler for patients.[214] Some prescribers may be hesitant to offer EHR systems because of concerns about cost, functionality, and data security.[215] For these reasons, the Commission believes it is important to allow prescribers the choice of whether to offer a digital delivery method to comply with the automatic-release requirement in the Eyeglass Rule, rather than mandating it.[216] The final rule neither compels prescribers to offer prescription-release by an electronic method nor requires that patients accept their prescription by electronic method when offered by the prescriber.

3. Comments Regarding Giving Patients a True Choice as to How To Have Their Prescription Delivered

Some commenters expressed concerns that not all patients may benefit from electronic access to their prescription, both as a result of limitations in broadband capabilities and due to differences in patient needs and health literacy that might affect patients' ability to access their prescriptions online.[217] Commenters asserted that patients must retain the ability to receive a paper copy of their prescription.[218] The challenges in educating patients on how to access their prescription on a portal were also noted by Workshop panelist Dr. Stephen Montaquila, a Rhode Island optometrist, who acknowledged that some patients prefer a paper copy.[219]

Other commenters described their experience with patients frequently losing or forgetting their prescription when going to order glasses. The commenters pointed to the remedy of having the prescription available on the portal, or noted that the patient could request a duplicate copy of the prescription or the seller could call to verify a prescription with the prescriber, and argued that these solutions should resolve concerns over prescription access and portability.[220] The Eyeglass Rule does not, however, require prescribers to respond to seller verification requests or provide duplicate copies of prescriptions, as is required by the CLR. The Commission also remains concerned about the

ongoing lack of understanding and limitations in patient access to portals or other health technology, and concludes that requiring all patients agree to digital delivery is not appropriate at this time.[221]

C. Additional Discussion and Commission Determination Regarding the Affirmative Consent to Digital Delivery

1. Final Rule Determination To Add Option for Digital Delivery of Eyeglass Prescriptions

The Commission agrees with the comments in favor of permitting, but not requiring, electronic delivery of the eyeglass prescription, provided consumers are informed about, and consent to, the delivery method. Based on its review of the record, the Commission is hereby modifying the Rule to require that prescribers provide patients with a copy of their prescription either (a) on paper or (b) after obtaining verifiable affirmative consent to digital delivery, in a digital format that can be accessed, downloaded, and printed by the patient. Obtaining such consent to digital delivery will require the prescriber to identify the specific method or methods of electronic delivery that will be used, and collect the patient's affirmative consent to the specified delivery method in a way that is verifiable, *i.e.,* can later be confirmed, such as through a signed consent form or electronic approval (as discussed below). Prescribers must then keep evidence of a patient's affirmative consent for a period of not less than three years. Patients who decline to consent, for any reason, must be given a paper copy of their prescription. Likewise prescribers who prefer to provide paper copies to their patients need not offer an electronic option.

Importantly, providing the option for digital delivery does not alter the prescriber's obligation to automatically provide the eyeglass prescription regardless of whether a patient requests it, but merely the method by which the patient will receive the prescription. It also does not impact the timing of prescription delivery. Whether the patient consents to digital delivery or opts for a paper copy of the prescription, prescribers must provide the prescription immediately after the eye examination is completed. As discussed above, it is critical that the patient be in receipt of their prescription before a prescriber offers to sell them eyeglasses, so as to ensure the separation of examination and dispensing under § 456.2, and to ensure that patients are able to freely comparison-shop for eyeglasses.[222] Accordingly, if a patient consents to the prescriber emailing or texting the prescription, or placing it on a portal, this method of delivery must take place at the end of the examination, and before the prescriber or prescriber's staff attempts to sell the patient eyeglasses.

The digital delivery option includes a recordkeeping provision, but, 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.'' [223] As detailed below, the Commission is modifying the proposed rule text to expressly recognize that consent to digital delivery can be obtained either on paper or in a digital format. In any case, obtaining and storing a record of patient consent should not take longer than obtaining and storing a patient's confirmation of prescription release,[224] and prescribers who use digital delivery to provide the prescription would not need to request that the patient acknowledge receipt of the prescription by signing a separate confirmation statement. 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.[225]

One related issue raised by some commenters is whether prescribers could obtain a patient's consent to digital delivery a single time rather than at every visit, and only need to obtain consent again if the prescriber changes their digital-delivery policy, a practice permitted by the Department of Health and Human Services with regard to its Notice of Privacy Practices signed-acknowledgement requirement.[226] Dr. Montaquila, for one, noted that allowing prescribers to obtain consent just once, when the patient first visits a practice, would lessen the Rule's burden for prescribers and yet still allow for the patient to be educated, opt-in knowingly, and have the opportunity to withdraw consent at a later time.[227]

The Commission notes that the Rule, as proposed in the NPRM and hereby adopted, does not specify that the verifiable affirmative consent must be obtained at every appointment. Instead, it requires the prescriber to provide the prescription on paper or ''in a digital format that can be accessed, downloaded, and printed by the patient, after obtaining verifiable affirmative consent, pursuant to § 456.3.'' The Commission clarifies that if the prescriber identifies the digital method that will be used for prescription delivery and allows the patient to choose whether to consent to that delivery method (rather than making it the default), then allowing patients to sign an authorization just once would satisfy the Rule's requirements. But as noted by the commenters, if the prescriber changes their digital delivery policies (for example, by switching from email delivery of prescriptions to access on a portal), they would need to re-obtain the patient's digital delivery consent. Additionally, prescribers should allow a patient to revoke consent at any time.

Further, the Commission believes that prescribers could use a single document to obtain verifiable consent to digital delivery of both contact lens and eyeglass prescriptions so long as it is clear to consumers that they are consenting to digital delivery for both. Ensuring that patients are aware of where to locate their prescriptions, and how to access them, should be a priority for prescribers, so regular re-education on these points is appropriate.[228]

Furthermore, § 456.3(c) requires that prescribers maintain records or evidence of a patient's affirmative consent for a period of *not less than* three years. It is important to note that if a prescriber intends to provide digital delivery to a patient for more than three years following that patient's signed consent, they should not dispose of the consent record after three years. Rather, the prescriber should retain the patient's signed consent for as long as the prescriber relies on it to authorize digital delivery of the prescription, plus another three years.[229]

2. Final Rule Moves Requirement for Obtaining Patient's Verifiable Affirmative Consent for Digital Delivery to a New Section and Out of Definitions

In the NPRM, the Commission proposed adding the digital delivery provision to the Rule as a new definition of the phrase ''provide to the patient one copy'' in § 456.1.[230] This definition would have stated both the option for the prescriber to offer the patient a digital copy of their prescription, and the requirements for obtaining verifiable affirmative consent to the digital delivery and maintaining a record or evidence of the patient's affirmative consent for a period of not less than three years. Adding this definition to the Rule would have mirrored the Commission's amendment of the CLR in 2020 to provide a similar

option for digital prescription delivery.[231]

Upon further consideration, the Commission has decided to move the digital delivery provision out of the definitions section and into § 456.2. By moving this language to § 456.2, the Commission seeks to ensure prescribers do not overlook the requirements for providing prescriptions digitally. Moving the digital delivery provision to this section may also make the requirement more noticeable and understandable to consumers. The FTC is also cognizant that the preferred drafting practice for regulations is to set out requirements in the body of the rule, rather than in the definitions.[232]

Accordingly, the Commission is amending § 456.2(a), ''Separation of examination and dispensing,'' to state that the automatic prescription release shall be provided on paper; or in a digital format that can be accessed, downloaded, and printed by the patient, after obtaining verifiable affirmative consent, pursuant to § 456.3. The Commission is then adding a new § 456.3 to the Rule titled, ''Verifiable affirmative consent to providing the prescription in a digital format.'' [233] New § 456.3 sets out the remainder of the text proposed in the NPRM as § 456.1(h)(2). It requires that when a prescription copy is provided in a digital format, the prescriber shall inform the patient of the specific method(s) of electronic delivery that will be used; obtain, on paper or in a digital format, 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, as specified in the new § 456.3.

Since the digital delivery provision, as adopted herein as § 456.3, was clearly proposed as § 456.1(h)(2) in the NPRM, moving the requirement to a new section in the Rule complies with the rulemaking requirements of both the Administrative Procedure Act and the FTC Act, while ensuring that regulated entities and the general public do not overlook the requirements because they were included in the definitions.[234] The Commission recognizes that the placement of the digital delivery provision in a new, dedicated section differs from the CLR, where it appears in the definitions. The requirements in each rule, however, are effectively the same. The Commission can amend the CLR during the next periodic rule review to mirror the Eyeglass Rule and, in the meantime, can provide clarity to prescribers through guidance materials.

3. Final Rule Adds Explicit Recognition of the Ability To Obtain Affirmative Consent on Paper or in a Digital Format

In this final rule, the Commission is amending the Rule to explicitly permit prescribers to obtain a patient's verifiable affirmative consent either ''on paper or in a digital format.'' This clarification comes in response to comments relating to permitting digital consent.

Participants at the workshop discussed that some EHR companies haven't updated their systems in light of the new CLR requirements to allow prescribers to collect signatures electronically, which would reduce the record-keeping burden.[235] Nevertheless, commenters suggested that the Rule should expressly permit prescribers to obtain patient signatures digitally or on paper.[236] For example, regarding the confirmation of prescription release, NAROC wrote, ''[t]he Commission may want to specifically allow for the signature to be an electronic signature by means of either a handwritten signature input onto an electronic signature pad or a handwritten signature input on a display screen with a stylus device. . . . While it is not clear to us how many optometry or ophthalmology offices use electronic signatures today, this clarification may pave the way for more offices to adopt this method of collecting a signature, making the confirmation process more efficient and less reliant on paper receipts in the future.'' [237] Dr. Montaquila acknowledged that some practices are already using electronic methods to capture patient signatures required by the CLR.[238]

Throughout the process of updating the CLR to permit digital prescription delivery and require confirmation of prescription release, the Commission acknowledged that prescribers may obtain a patient's signature either on paper or digitally. In the NPRM for the Contact Lens Rule review, the Commission proposed, ''[t]he acknowledgment form shall be in a format that allows either conventional or electronic signatures. Prescribers may maintain copies of the acknowledgment forms in paper or electronically.'' [239] In the SNPRM for the CLR, the Commission stated, ''[t]he precise wording of such confirmations would be left to the prescriber's discretion, but for prescribers opting for (a), (b), or (c), a patient's written or electronic signature would always be required.'' [240] Similarly, when proposing changes to the Eyeglass Rule in its NPRM, the Commission noted the ''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.'' [241]

The Commission finds the Rule is improved by explicitly permitting prescribers to obtain a patient's verifiable affirmative consent either ''on paper or in a digital format.'' Accordingly, §§ 456.3 and 456.4, setting forth the requirement for obtaining a patient signature confirming prescription receipt, allow prescribers to meet the requirements of these provisions by obtaining the patients signature either ''on paper or in a digital format.'' [242] This will resolve prescriber confusion regarding the need to print out digital forms and collect wet signatures that might then need to be scanned and stored electronically in an EHR system. Alleviating prescriber misunderstanding regarding signature collection should help reduce waste and facilitate faster, more efficient Rule compliance.[243]

4. Final Rule Clarifies That Digital Delivery Methods Identified in Affirmative Consent Request Must in Fact Be Used

The Commission recently sent cease and desist letters to prescribers of contact lens prescriptions and eyeglass prescriptions in response to consumer complaints that the prescribers did not release their prescriptions at the end of the contact lens fitting or eye examination, or otherwise violated the CLR or Eyeglass Rule.[244] As discussed at the workshop, in subsequent communications with letter recipients, Commission staff obtained samples of forms some prescribers were using to comply with the CLR consent-to-digital-delivery and confirmation-of-prescription-release requirements. Staff noted, ''[w]e've seen forms where there's not a separate signature about digital consent. We've also seen forms where the information is included in an intake form among a lot of other information that the patient may not see. And in some cases, the specific method of electronic delivery is not necessarily identified. It may say, 'We will provide you with your prescription digitally either by text, email, or portal.' '' [245]

The Commission is concerned that patients cannot provide informed consent to digital delivery if prescribers do not identify the delivery method that will be used. Patients will not know where to locate their prescription if they are not told which delivery method the prescriber plans to use. This can result

in the patient effectively not receiving the prescription, as required by the Rule. Similarly, providing a disclosure about digital delivery as part of a long form containing unrelated information, such as privacy practices and payment policies, and then requesting one signature at the end of the form might not be an effective way of obtaining the ''verifiable affirmative consent'' required by the Rule. Dr. Beatty noted that decoupling information during intake related to patient consent may be appropriate to ensure patients are understanding and agreeing to digital delivery.[246]

In addition, providing a copy of the prescription electronically by default while notifying patients that they can request a paper copy if they want one undermines the automatic-prescription-release requirement by converting it to a release-upon-request model that the Commission has rejected.[247] As an example, one of the sample forms shown at the workshop stated, ''I acknowledge the [Prescription Access] policy and note I can (i) access my eyeglass and contact lens prescriptions digitally at [website redacted] or (ii) obtain a paper copy at any time as well.'' [248] This language essentially transforms it into a notice of digital delivery rather than a true patient consent to digital delivery. In satisfying the Eyeglass Rule's automatic-prescription-release requirement, the patient must be given an actual choice to select an identified electronic delivery method or to receive the prescription on paper automatically. Prescribers are free to also place prescriptions on a portal, but this action would not satisfy the requirements of § 456.2 if the patient did not opt-in to the digital delivery option.

To provide clarity to prescribers, the final rule, in § 456.3(a), states that the prescriber shall, ''identify to the patient the specific method or methods of electronic delivery *that will* be used,'' rather than ''to be used,'' as was proposed.[249] The digital delivery method or methods the prescriber identifies to the patient when seeking consent should be the method the prescriber actually uses. It would not be appropriate, for example, for a consent form to state, ''I authorize my eye doctor to provide me with a digital copy of my prescription via email, text, and/or the secure online patient portal at the completion of my contact lens fitting and/or refractive eye examination,'' unless the prescriber did in fact deliver the prescription using all of the referenced methods.

IV. Final Rule Pertaining to Confirmation of Prescription Release

A. Proposed Confirmation Requirement in the NPRM and the Basis for Such Proposal

After considering the evidence discussed in sections I and II, *supra,* including comments submitted in response to the ANPR, the Commission proposed in the NPRM to amend the Rule to add a confirmation-of-prescription-release requirement. In so doing, the Commission stated its belief that such confirmation would increase the number of patients who receive their prescriptions, inform patients of the Rule and of 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 prescribers and consumers, and bring the Eyeglass Rule into congruence with the confirmation-of-prescription-release requirements of the Contact Lens Rule.[250]

As a result, in the NPRM, the Commission proposed a new § 456.3 [251] to require 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.

Proposed § 456.3 further provided that if the prescriber elects to confirm prescription release via paragraphs (a)(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 (a)(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.'' [252]

The Commission then sought public comment on the benefits and burdens of its confirmation-of-prescription-release proposal.[253] The Commission also invited comment on whether the proposed change would affect Rule compliance, the Commission's ability to enforce the Rule, or patient's understanding of their rights under the Rule.[254]

B. Comments on the NPRM and Discussion at the Workshop Regarding Confirmation of Prescription Release

1. Comments in Favor of Confirmation-of-Prescription-Release Proposal

The record contains numerous comments in support of the confirmation-of-prescription-release amendment, with these comments detailing the need for, and benefits of, the proposed amendment. Reasons given in support of the amendment include: that it will bring greater awareness of a consumer's right to their prescription, greater compliance with automatic prescription release,[255] and a greater ability for the Commission to enforce the Rule; that the acknowledgment will serve as evidence of compliance for prescribers; and that benefits flow from having the Eyeglass Rule's confirmation requirement match that of the Contact Lens Rule. Other commenters generally support the Rule, but did not provide specific reasons for their support.[256]

NAROC, calling the confirmation proposal needed and simple,[257] stated that it would result in greater compliance and wider consumer understanding of their rights.[258] In addition, according to NAROC, the proposal would allow all sellers in the market for corrective eyeglasses to participate. Specifically, NAROC stated support for requiring confirmation since ''evidence demonstrates that despite the many years that the [automatic prescription release] requirement has been in effect, not all consumers are aware that they should receive an eyeglass prescription without requesting it.'' [259] Consumer Action, likewise,

called the confirmation proposal ''consumer-friendly'' and discussed it as a way to remedy a lack of compliance, a lack of consumers awareness of their automatic right to a copy of a prescription, a lack of competition, and a reduced ability to shop around for lower prices.[260]

Other commenters reiterated that the confirmation proposal would increase compliance with automatic prescription release. The advocacy organization National Taxpayers Union supported requiring confirmation to ''strengthen the process of providing consumers with a copy of their eyeglass prescription,'' which will benefit consumers.[261] 1–800 CONTACTS stated the ''confirmation proposal will bolster prescription portability, promoting consumer choice and competition in the evolving market for prescription eyewear.'' [262]

Commenters specifically spoke to the proposed amendment's ability to assist the Commission in enforcing the Rule's automatic-release requirement. 1–800 CONTACTS stated its desire for greater enforcement of the Rule and expressed disappointment that the Commission has only issued warning letters since enacting a similar requirement for the Contact Lens Rule in 2021.[263] NAROC commented that both the confirmation of prescription release and the three-year recordkeeping requirement will make the Rule easier for the FTC to enforce. The organization stated that prescribers have a responsibility to provide evidence that the patient received a copy of the eyeglass prescription at the end of the exam, and that confirmations of prescription release are helpful to prescribers to show their compliance in instances when patient complaints of non-compliance are brought before them.[264] At the workshop, Joseph Neville of NAROC added that, if the FTC was going to regularly enforce the Rule, the prescriber needs proof they actually complied, and the acknowledgment will serve that purpose.[265] NAROC likened the confirmation proposal to prescribers asking their patients to acknowledge receipt of privacy practices, to give consent to certain treatments or procedures, and to allow providers to share protected health information in certain situations.[266] According to NAROC, such acknowledgments benefit the prescriber by averting disputes as to what the patient agreed.

At the workshop, Wallace Lovejoy opined that it is appropriate to encourage some sort of recordkeeping that the prescription was in fact delivered to the patient due to ''the unique nature of the market and a significant amount of financial interest on the part of prescribing and dispensing optometrists'' [267] Indeed, NAROC commented that prescribers have a powerful incentive to improve the ''capture rate'' of in-office eyewear sales to their patients since they still make most of their revenue from selling the eyewear that they prescribe.[268]

NAROC also stated that the significant benefits of the proposed confirmation would exceed the minimal burdens. Its comment stated that the ''amendments should not have significant or disproportionate impact on prescribers' costs'' and that its member experience and observation indicates that ''thousands of optometrists affiliated in co-location with NAROC member companies regularly comply with the current Eyeglass Rule and the Contact Lens Rule [which already contains a confirmation-of-prescription-release requirement] with little added cost or other burden on the eye care practice.'' [269] NAROC said it has not seen any credible evidence that the requirement is overly burdensome or will result in anything more than a trivial expense. In response to requests from their members for information as to whether the added effort of confirmations for contact lens prescriptions was a problem, they heard that compliance is occurring with little or no disruption or expense.[270]

Pete Sepp, the president of the National Taxpayers Union, said he supports the Rule and the confirmation proposal, but is very cognizant of regulatory burdens imposed on prescribers. He said the key question for him is whether the extra burden the confirmation brings is a problem, or alternatively, whether the problem may derive rather from the overall burden from all regulations imposed on prescribers.[271]

The National Taxpayers Union (NTU) suggested that the Commission may have underestimated the confirmation burden, particularly the 10-second estimate for how long it takes for consumers to read and sign the confirmation statement.[272] It also stated it was likely the burden would have a disproportionate impact on smaller, less sophisticated, prescribers who lack economies of scale and equipment, and thus merely averaging the burden cost among all of the nation's eyecare prescribers was an ''oversimplification.'' [273] According to NTU's estimate, a ''modest optometry establishment'' performing 3,000 examinations a year would—based on the Commission's NPRM estimates for time and labor—increase the paperwork burden by 167 hours and incur an additional labor compliance cost of $4,123, ''not an inconsiderable burden for a small establishment.'' [274] Sepp of the NTU did suggest, however, that compliance with the confirmation-of-prescription-release proposal ''might not be quite as burdensome'' when comparing it to the overall regulatory burdens on prescribers, and that perhaps the real focus should be on reducing overall burdens that hamper small businesses.[275]

One factor worth noting for the confirmation proposal, according to NAROC, is that having a similar confirmation requirement for the Eyeglass Rule, as already codified in the Contact Lens Rule, should lessen the additional incremental burden of the proposed amendment to the Eyeglass Rule, since most contact lens wearers also receive eyeglass prescriptions and should get them at the same time.[276] NAROC also stated that the similar requirement for the Eyeglass Rule should ease issues with compliance and staff training.[277]

2. Comments Against the Confirmation-of-Prescription-Release Proposal

Some commenters, largely prescribers and prescriber trade associations, were critical of the confirmation-of-prescription-release proposal, stating that existing strong compliance with the automatic-prescription-release requirement of the Eyeglass Rule makes the proposed confirmation requirement unnecessary, and that the confirmation proposal is burdensome.[278]

The American Optometric Association opposed the proposed confirmation requirement for a number of reasons. As noted above in the discussion regarding automatic-release compliance, the AOA asserts that the requirement is unnecessary because it disputes that there is any issue with prescription-release compliance.[279] In addition, the AOA asserted that a confirmation requirement would not have a significant and meaningful impact on competition and choice and in support cited the (previously discussed) NERA survey for the propositions that: (1) three in five Americans do not believe that additional paperwork requirements in their doctor's offices would make them more aware of their rights; (2) nearly half indicated the amount of paperwork they currently do is overwhelming; (3) 41% indicated that the complexity of the paperwork is overwhelming; and (4) approximately 20% of those surveyed did not even remember the purpose of the paperwork they have to complete at a doctor's appointment.[280] Based on these results, the AOA concluded that

''it is inaccurate to say that a new paperwork requirement for eyeglass prescriptions can lead to increased competition and choice.'' [281]

Further, the AOA expressed concern that the confirmation requirement would have a disproportionate burden on small business, given the fact that many of its members have a small staff, high staff turnover, and face challenging economic pressures, including increased overhead and costs.[282] In fact, according to AOA, the NERA survey data supports its position that the FTC ''significantly underestimated'' how long it takes to confirm prescription release.[283] According to the AOA, a large percentage of its members report that it takes 30 seconds or more to obtain the patient's signed confirmation and ''[e]ssentially, doctors of optometry have reported that the time burden is *at least* 3 times the FTC's estimated burden.'' [284] (emphasis in original). The AOA requested that the Commission reconsider whether there is an urgent need at this time for the confirmation-of-prescription-release amendment.[285]

Individual prescribers share some of the same concerns voiced by the AOA. At least two commenters stated that the proposed confirmation is a burdensome solution to a problem that does not exist.[286] A number of commenters, some of whom commented anonymously, stated that the confirmation is unnecessary, costly, intrusive, and would be time-consuming and take away from patient care.[287] Optometrist Dr. David Durkee suggested that adding the burden of another confirmation requirement would be counterproductive and likely just lead to more prescriber non-compliance.[288] At the workshop, Dr. Michaels stated that there is a lot of time, effort, and discussion required when prescribers ask their patients to sign confirmations.[289] Dr. Montaquila explained at the workshop that for contact lens prescriptions, it takes his ''very best staff about four minutes to complete the [confirmation and prescription release] process, from explaining why we're doing it to the patient, providing them with their prescription, making the copies, providing their prescription back to them, and ultimately storing it.'' [290] He stated that the office devotes about 1.5 full time employees to all of the office's compliance issues and that adding more rules [to the Eyeglass Rule] will only increase costs to the practice.[291] Dr. Montaquila also noted that the burden is recurring (as opposed to a one-time expense) since each time prescribers provide a prescription, a confirmation will be needed.[292] Dr. Masoudi questioned whether multiple confirmations are needed when multiple prescriptions are provided, and claimed that that would also increase the burden of compliance.[293]

The AAO also disagreed that the burden would be minimal, noting that it would particularly hit hard on small practices that may not utilize electronic health record systems.[294] AAO further argued that, without better evidence of non-compliance, the confirmation-of-prescription-release amendment should not be imposed, and asked the Commission to identify alternative mechanisms to address actions of noncompliant prescribers.[295] Dr. Repka also noted at the workshop that he has not seen a benefit for either the prescriber or the consumer in the contact lens space since enactment of the confirmation requirement in the Contact Lens Rule.[296]

Some commenters pointed to differences between the eyeglass and contact lens markets to support their position that the Eyeglass Rule should not contain the same confirmation requirement as exists in the Contact Lens Rule. Dr. Montaquila argued that there is a greater burden associated with the Eyeglass Rule proposal due to the greater volume of eyeglass wearers—165 million eyeglass wearers versus 45 million contact lens wearers.[297] Dr. Repka pointed out that the average eyeglass wearer is much older than the average contact lens wearer and that the older population may be more easily concerned about multiple signature lines.[298]

3. Comments About the Exemption for Prescribers Who Do Not Have a Direct or Indirect Financial Interest in the Sale of Eyeglasses

In the NPRM, the Commission proposed to exempt prescribers who do not have a direct or indirect financial interest in the sale of eyeglasses from the proposed signed confirmation-of-prescription-release requirement.[299] Direct or indirect interest in the sale of eyeglasses would include, but not be limited to, an association, affiliation, or co-location with prescription-eyewear sellers.[300] The Commission requested input on the question, ''Aside from associations, affiliations, and co-locations with prescription-eyewear sellers, what other indirect financial interests exist in the sale of prescription eyewear that should disqualify a prescriber from the proposed exemption?'' [301] There were no written comments in response to the NPRM or workshop on this point.[302]

At the workshop, Joseph Neville floated the idea of applying the exemption more broadly. Specifically, he said that for the Contact Lens Rule, NAOO, the predecessor to NAROC, suggested that prescribers who were affiliated in a co-location situation should be exempt from the signed acknowledgment requirement.[303] He explained that when an optical company leases space to a prescriber, the prescriber does not sell the eyeglasses, and thus, the exemption should apply. Yet, he acknowledged that the Commission previously rejected that position and in concluding his comments, he supported the Commission's proposal to limit the exemption to those who are solely involved in clinical and not connected in any way with sales.[304]

4. Comments About Alternatives to the Confirmation-of-Prescription-Release Proposal

As possible alternatives to the signed acknowledgement proposal, commenters at the ANPR stage recommended conspicuous signage regarding consumers' right to a copy of their prescription, or an eye care patients' bill of rights, notifying consumers of their rights under the Rule.[305] Some commenters seemed to suggest that there is a greater need for the FTC or prescribers to educate consumers or to enforce the Rule as is, as opposed to amending the Rule to include a confirmation of prescription release.[306] For instance, the AOA opposed the Commission's NPRM proposal, and asserted that the Commission should focus its energies on scrutinizing the sales of online retailers, and advising the public about ''risks'' arising from purchasing glasses online.[307] Meanwhile optometrist David Durkee recommended that instead of adding the confirmation requirement, the Commission should increase enforcement through random audits, inspections, fines, and increased publicity about such penalties.[308]

C. Additional Discussion and Commission Determination Regarding the Confirmation-of-Prescription-Release Proposal

1. Final Rule Determination To Amend the Rule To Require Confirmation of Prescription Release

The Commission has carefully reviewed and analyzed all of the evidence in the record, including the 868 comments submitted in response to its ANPR, 27 comments submitted in response to its NPRM, the discussion at the 2023 Eyeglass Rule workshop, 20 comments after the workshop, and when appropriate, the record from the

Commission's recent review of the Contact Lens Rule. This record, in conjunction with the historical impetus for the Rule and the Commission's enforcement and oversight experience, has led to a Commission determination to amend the Rule to add a confirmation-of-prescription-release requirement.

The evidence demonstrates that the automatic-release requirement remains the optimal remedy for prescribers' continued failure to release prescriptions, and yet lack of compliance with the automatic-release provision hampers the effectiveness of this remedy.[309] The evidence also demonstrates that consumers lack an awareness of their rights to a copy of their eyeglass prescription, and thus may be unable to remedy a prescriber's failure to release prescriptions on their own.[310] Having determined that it would be beneficial to increase compliance with, and awareness of, the automatic-release provision, the Commission has determined that the best way to achieve this goal is to amend the Rule to add a new requirement to the existing automatic-release remedy. By modifying and improving the remedy for prescribers' failure to release a prescription, it will not only increase the number of patients who receive their prescriptions and learn of their right to possess their prescriptions, but will also: 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 prescribers and patients, and substantively bring the Eyeglass Rule into congruence with the Contact Lens Rule in terms of the confirmation-of-prescription-release requirement.

This remedy also solves the ''evidentiary squabbles'' issue as to whether a prescriber complied in a specific instance, or complies routinely with prescription release. As explained in the NPRM, 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.[311] In fact, due in part to the difficulty of ascertaining whether a prescriber violated the Rule, the Commission has only brought one enforcement action against an eyeglass prescriber for failure to comply with the automatic prescription release.[312] The confirmation-of-prescription-release requirement will improve and simplify its ability to assess and verify compliance with the Rule's automatic prescription release requirement. It will also make it easier for prescribers to prove that they did, in fact, provide prescriptions to patients who claim otherwise.

a. Alternatives to Confirmation of Prescription Release Not Adopted

The Commission is not adopting the alternative remedies proposed by some commenters. First, as explained above, no new comments or evidence was submitted following the NPRM regarding the proposal to require conspicuous signage in prescribers' offices stating consumers' rights to their prescriptions, and, likewise, no new comments or evidence submitted with respect to a consumer Bill of Rights.[313] Since the Commission had previously decided, for the reasons outlined in the NPRM,[314] not to adopt these measures, the Commission has no reason to revisit and alter its decision.

For a number of reasons, the Commission also declines to adopt the proposal that the Commission focus on additional consumer education in lieu of adopting the signed confirmation of prescription release. First, relying on such an approach would improperly shift the burden of prescription-release compliance and enforcement to the consumer, an approach the Commission has repeatedly rejected in the past.[315] Second, the Commission resolves that educating consumers at their appointment about their right to their prescription is more targeted and impactful than other methods of consumer education alone in which a consumer is not asked to read and provide a signature. Lastly, the AOA's suggestion in its NPRM comment to educate consumers about the potential risks from purchasing eyeglasses online would do nothing to increase prescription release. In fact, the suggestion appears unrelated to the issues under discussion in the NPRM or this final rule.

Although the Commission declines commenters' suggestions that it rely on greater consumer education in lieu of a signed confirmation requirement, as discussed in section IV.B.4, *supra,* the Commission agrees there is a need to bolster its existing guidance on the Eyeglass Rule, as an added measure to inform consumers of their rights, and businesses of their obligations, under the Rule.

As for the suggestion that the Commission increase enforcement of the existing automatic-release provision in lieu of adding a confirmation requirement, the Commission addressed this in the NPRM, noting that the Commission recognizes the need for increased enforcement, but that 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.[316] 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.[317]

b. The Burdens of the Confirmation of Prescription Release Are Not Substantial

The evidentiary record does not establish that the burden of the confirmation-of-prescription-release requirement will have a substantial financial impact on prescribers. Prescribers already comply with a similar requirement for contact lens prescriptions, and it should require a minimum of additional time, effort, and training to include eyeglass prescriptions. Some prescribers may already be getting patient confirmations for eyeglass prescriptions, since it does not make much sense to obtain confirmations for contact lenses but not for eyeglasses, and the patient confirmation provides the prescriber with tangible proof that they complied with the existing prescription-release requirement. In its Paperwork Reduction Act (''PRA'') analysis, the Commission doubled the previously estimated time it takes for prescribers' offices to obtain a signed patient confirmation, and yet even doubled, it is still merely 20 seconds. In reality, it may even take less, and some industry estimates appear to be based on faulty presumptions.[318] Furthermore, the ongoing transition to digital recordkeeping will continue to reduce the burden, both in terms of record preservation and obtaining patient signatures. The final rule's overall estimated financial burden for the confirmation-of-prescription-release requirement of $38,389,993 amounts by one estimate to approximately $629 in additional annual administrative costs per eye care provider.[319]

The Commission also does not find the AOA's paperwork survey, summarized in its comment, as compelling evidence for its position that ''it is inaccurate to say that a new

paperwork requirement for eyeglass prescriptions can lead to increased competition and choice.'' [320] A review of appendix A attached to its comment shows that the following survey question was asked of 1,063 respondents: ''Thinking about your experience, both virtual and in-person, with doctors in general, please select your level of agreement with the following statements.'' The statements included in the survey were: (1) ''I generally remember the purpose of the paperwork I complete at a doctor's appointment''; (2) ''The amount of paperwork I have to complete at a doctor's appointment is overwhelming''; (3) ''The complexity of the paperwork I have to complete at a doctor's appointment is overwhelming''; and (4) ''Having to sign more paperwork at a doctor's appointment would make me more aware of my patient's rights.'' The options provided to the respondents for each statement are: ''Completely agree,'' ''Somewhat agree,'' ''Neutral,'' ''Somewhat disagree,'' and ''Completely disagree.'' [321]

These questions, and the extent to which consumers agree or disagree with them, may reveal the unsurprising fact that most people do not appreciate doing ''paperwork,'' but do not display anything of import related to this rulemaking. By asking generalized questions about ''paperwork''—a term with a negative connotation—and ''patient's rights,'' without explaining to respondents the context or what rights they are referring to, the survey loses its informational value. It does not reveal what consumers think about a confirmation-of-prescription-release requirement, about whether they would appreciate having a copy of their prescription, about whether they understand their right to their prescription, or even about their experiences with any particular documents provided to them by eye care prescribers.[322]

Aside from the fact that these survey questions are too vague and generalized to serve as a gauge as to the usefulness of a confirmation-of-prescription-release requirement, the survey questions may even indicate that some paperwork can serve a purpose. According to the survey, 62% of Americans respond that they generally remember the purpose of the paperwork they complete at a doctor's appointment, with another 19% remaining neutral on this question; and 40% agree with the statement, ''having to sign more paperwork at a doctor's appointment would make me more aware of my patient rights,'' with another 30% responding neutrally.[323] While these percentages do not reveal anything about the confirmation-of-prescription-release requirement, they could, in fact, support the general position that many Americans do remember information from the paperwork they fill out at their doctors' offices, and that the paperwork can serve to make them somewhat more aware of their general rights. Of greater significance for this rulemaking, however, is the fact that the confirmation-of-prescription-release requirement is not solely intended to educate consumers about their rights. While that is one purpose, the requirement is also intended to remind prescribers' offices to provide patients with their prescriptions, and to create a mechanism for prescription-release verification and enforcement. Therefore, the Commission finds that the signed confirmation of prescription release (a form of ''paperwork'') will increase prescriber compliance, and that will lead to increased competition that benefits consumers.

The Commission also carefully considered information and comments on the record that question the Commission's estimate of time for confirming prescription release, including the separately conducted AOA survey of its members submitted in support of its statement that the FTC ''significantly underestimated'' the length of time it would take for prescribers to confirm prescription release. As discussed more fully in the Paperwork Reduction Act section (section VIII of this SBP), the Commission has decided to increase the estimated time to obtain a patient confirmation signature.[324]

Although the Commission does not find the burdens of the confirmation of prescription release to be substantial, the Commission is sensitive to the concerns raised by the AOA and others regarding the burden on prescribers, many of whom are small businesses. In an attempt to minimize these burdens, the Rule provides prescribers with both digital and paper options for methods to comply,[325] and provides one-sentence sample language that prescribers can use when providing paper copies of prescriptions should they wish to use it. As for concerns that the burden is ongoing since each time a prescriber provides a prescription a confirmation is needed, the Commission notes that many prescribers may offer and consumers may accept a digital delivery of the prescription, and as previously discussed, may not need to ask for affirmative consent to digital delivery for every new visit.[326] As for paper copies of prescriptions, over time consumers should become more familiar with the request for their signature to confirm prescription receipt and thus, the staff time to handle possible questions or to otherwise comply with the confirmation of prescription release should decrease.[327] The Rule also has an exemption for those without a direct or indirect financial interest in the sale of eyeglasses. Moreover, this amendment aligns with the prescription release related provisions of the Contact Lens Rule, thereby reducing the confusion and complexity that might arise for consumers and prescribers from having different confirmation-of-prescription-release requirements for contact lens and eyeglass prescriptions. In addition, the marginal cost of the amendment to the Eyeglass Rule should be relatively low because the CLR already requires prescribers to obtain confirmation of prescription release and to maintain records of such. Some prescribers likely have forms and systems in place already, which may need only minor adjustments to accommodate confirmations for eyeglass prescriptions.[328]

c. Exemption for Prescribers Who Do Not Have a Direct or Indirect Financial Interest in the Sale of Eyeglasses

The Commission also adopts without modification proposed § 456.3(c), which provides an exemption to the confirmation-of-prescription-release requirements for prescribers who do not have a direct or indirect financial interest in the sale of eyeglasses.[329] Direct or indirect financial interest in the sale of eyeglasses includes, but is not limited to, an association, affiliation, or co-location with prescription-eyewear sellers.[330] The Contact Lens Rule contains a parallel exemption.[331] The purpose of such an exemption is to reduce the burden on prescribers who do not sell lenses, and therefore, have no incentive to withhold prescriptions.[332] Although Joseph Neville of NAROC questioned whether co-location arrangements should be considered as having an interest in the sale of eyeglasses, the Commission finds that co-location arrangements could create a financial incentive for prescribers to withhold a prescription, and thus, should be required to comply with the confirmation requirement. If a prescriber has uncertainty as to whether the exemption applies, they should err on the side of caution by complying with the confirmation-of-prescription-release requirement.[333] Since there was no opposition to the proposal relating to the exemption, the Commission adopts § 456.3(c) as proposed.[334]

2. Comments About Options for Obtaining the Confirmation and Commission Determination

The Eyeglass Rule NPRM proposed in § 456.3(a) the same options to confirm prescription release of eyeglass prescriptions as the options available to confirm prescription release of contact lens prescriptions in the Contact Lens Rule. They consist of: (i) a signed statement confirming receipt of the prescription; (ii) a prescriber-retained copy of a contact lens prescription that contains a statement confirming receipt of the prescription; (iii) a prescriber-retained copy of the receipt for the examination containing a statement confirming receipt of the prescription; and (iv) if a digital copy of the prescription was provided to the patient, retain evidence that the prescription was sent, received, or made accessible, downloadable and printable.[335] Workshop participants discussed these options in the context of the Contact Lens Rule in order to recommend for or against their inclusion in the Eyeglass Rule's confirmation requirement.

a. Comments at the Eyeglass Rule Workshop

At the workshop, Dr. Montaquila discussed the ''range of approaches'' prescribers use to comply with the CLR's confirmation-of-prescription-release requirements and provided concrete examples of the way some of the options are currently in use. He called option (a)(1)(i), the signed statement option, a flexible option currently in use. But, he stated that, for some offices that have electronic health records, offices must print the prescription from the electronic health records systems, request a signature, scan or retain the prescription with the acknowledgment, and store the acknowledgment.[336] He provided an example of a template form that he said is in use by many offices.[337] This form, entitled ''Contact Lens Prescription Signed Acknowledgment Form'' is recommended by the AOA to its members and is in its ''Contact Lens Rule Compliance Toolkit.'' [338] The form contains six paragraphs, with the first stating, ''Included below is important information to review prior to receiving your contact lens prescription.'' The middle three paragraphs consist of advice, attributed to the Centers for Disease Control and the Food and Drug Administration, on healthy contact lens wearing habits, and include recommendations such as ''Schedule a visit with your eye doctor at least once a year'' and ''Understand that eye infections that go untreated can lead to eye damage or even blindness,'' among others. The fifth paragraph presents five bullet points listing common symptoms of an eye infection, such as ''Irritated, red eyes,'' ''Light sensitivity,'' and ''Sudden blurry vision.'' The last paragraph, directly above a patient signature and date line, states, ''Sign below to acknowledge that you were provided with a copy of your contact lens prescription at the completion of your contact lens fitting.''

As for proposed § 456.3(a)(1)(ii), in which prescribers retain signed copies of contact lens prescriptions that contain a statement confirming receipt of the prescriptions, Dr. Montaquila stated that the AOA assists prescribers who use this option by providing carbon-copy prescription pads.[339] With this method, the prescriber writes the prescription, the patient signs the confirmation statement on the prescription, and the patient and prescriber each retain a copy. Dr. Montaquila then implied that this paper option was less convenient or accurate because 88% of office-based physicians have transitioned to EHRs.[340] According to Dr. Montaquila, some prescribers are handwriting prescriptions after generating a prescription in an electronic health record, and this duplication increases cost, time, and the possibility for errors.[341] In support of his assertion about greater errors from handwritten prescriptions, he cited to a Weill Cornell Medical College study of drug prescriptions finding error rates in 30 per 100 written prescriptions versus seven per hundred in electronic prescriptions.[342] He stated that some EHRs permit prescriptions containing statements of confirmation to be printed, but this creates a different problem because once it is signed by the patient, the office ''needs to take that prescription back, copy and perhaps scan it and then retain that for three years.'' [343]

Section 456.3(a)(1)(iii) of the NPRM Eyeglass Rule confirmation proposal (and existing Contact Lens Rule confirmation requirement) allows prescribers to retain a signed statement confirming prescription receipt on a copy of the examination payment receipt. According to a 2023 AOA survey of optometrists, about 15% of prescribers said they use this method,[344] but Dr. Montaquila stated that he had not found that any of his colleagues had a payment system in place that would allow for the use of this method with respect to the confirmation of contact lens prescription release.[345]

Dr. Montaquila also addressed the digital release option, proposed § 456.3(a)(1)(iv), which allows a prescriber, with the patient's affirmative consent, to release the prescription digitally so long as they retain evidence that the prescription was sent, received, or made accessible, downloadable and printable. In discussing this option, he displayed a model consent form used by many practices for contact lens prescription release entitled ''prescription access notice policy statement.'' The model form states that access to prescriptions is available to patients digitally and that physical copies of prescriptions are available, and provides a place for a patient signature. He noted that the electronic prescription-release approach can take many forms depending on what's available to the practice, and that some forms default to the patient agreeing to receive the prescription digitally, with a paper version available upon request.[346]

b. Commission Determination Regarding Options for Obtaining the Confirmation

The final rule, § 456.4(a)(1), replaces the four options from the NPRM with two broader options in paragraphs (a)(1)(i) and (ii) that encompass the options proposed in the NPRM, but also ensure prescribers have flexibility and choice in how they obtain their confirmations. The first option, § 456.4(a)(1)(i), covering instances where prescribers provide a *paper copy* of the prescription, provides that the prescriber must request that the patient acknowledge receipt of the prescription by signing a separate statement confirming receipt of the prescription. Section 456.4(a)(1)(i) adopts the proposed § 456.3(a)(1)(i) with modifications so that it encompasses the proposed § 456.3(a)(1)(ii) (where a prescriber can retain a copy of a prescription that contains a signed statement confirming receipt of the prescription) and proposed § 456.3(a)(1)(iii) (where a prescriber can retain a signed copy of the sales receipt for the examination that contains a statement confirming receipt of the prescription). The NPRM's proposed § 456.3(a)(1)(ii) and (iii) are essentially examples of documents—prescriptions and sales receipts—that can contain separate statements confirming receipt of the prescription, and these methods of obtaining confirmation continue to be permitted under the final rule's broader option § 456.4(a)(1)(i).

The Commission adopts § 456.4(a), which requires that the statement confirming receipt be separate. Prescribers should provide a signature line that clearly and conspicuously applies to a statement of confirmation that the patient has received their

prescription. If instead it is part of a multi-paragraph form containing unrelated information, such as advice about contact lens wear and care habits or the symptoms of eye infections, which then requests a signature at the end of the form, it may not be a valid method to request confirmation of prescription release. While additional information supplied on the model form may be useful to patients, it can confuse patients as to what it is they are signing for, and add additional time to the confirmation obligation. Indeed, as discussed in this document's PRA analysis section, the use of a model template from AOA containing several additional paragraphs unrelated to the confirmation requirement may well contribute to some prescribers' claims that it takes more than 10 seconds to obtain a contact lens prescription confirmation from a patient.[347]

Section 456.4(a)(1)(ii) applies to instances where the prescriber provides a digital copy of the prescription to the patient and is, with one minor alteration,[348] the same as the NPRM's proposed § 456.3(a)(1)(iv). If a prescriber provides the prescription digitally, after obtaining verifiable affirmative consent, the prescriber need not request the patient sign a separate statement confirming receipt. However, the prescriber does need to retain evidence that the prescription was sent, received, or made accessible, downloadable, and printable. In the final rule's § 456.4(a)(1)(ii), that evidence serves as the ''confirmation of prescription release.''

The Commission recognizes that by altering its NPRM proposal in this manner, the options for obtaining confirmation of prescription release in the Eyeglass Rule will not precisely mirror the language of the options provided in the Contact Lens Rule, but these are differences in textual language, not the Rules' policy or effects. The obligations for prescribers with respect to when and how to offer a prescription, and how prescribers can obtain and store a confirmation of receipt, are essentially the same for contact lens and eyeglass prescriptions. For clarity purposes, the Commission may address the language differences in the CLR's next periodic rule review. For these reasons, the Commission adopts § 456.4(a) as set out in this final rule.

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

3. Final Rule Modification To Add Explicit Recognition of a Prescriber's Ability To Obtain a Confirmation on Paper or in a Digital Format

If the prescriber provides a paper copy of the prescription to the patient, the prescriber must request that the patient acknowledge receipt by signing a separate statement confirming receipt of the prescription. As discussed above with respect to obtaining signatures of affirmative consent to digital delivery, participants at the workshop discussed that some EHR companies haven't updated their systems in light of the new CLR requirements to allow prescribers to collect signatures electronically, which would reduce the record-keeping burden, and suggested that the Rule should expressly permit prescribers to obtain patient signatures digitally or on paper.[349] Specifically, at the workshop, Dr. Repka stated that the electronic medical records of the future will be able to accept electronic signatures that will be stored in ways other than on paper and says, ''if there's an option to do that, it would be nice. If you still needed it to be on a printable PDF, then not as convenient.'' [350]

When proposing changes to the Eyeglass Rule, the Commission noted the ''recordkeeping burden could be reduced to the extent that prescribers have adopted electronic medical records systems, especially those where patient signatures can be recorded electronically and inputted automatically into the electronic record.'' [351] The Commission resolves therefore to change the Rule to explicitly state that obtaining patient signatures ''on paper or in a digital format'' is permissible and complies with the Rule. Accordingly, § 456.4 of the final rule sets forth this language. The Commission believes this will resolve prescriber confusion regarding the need to print out digital forms and collect wet signatures that might then need to be scanned and stored electronically in an EHR system. As with electronic collection of patient consent to digital delivery, alleviating prescriber misunderstanding regarding signature collection should help reduce waste and facilitate faster, more efficient, Rule compliance.[352]

V. Final Rule Pertaining to Proof of Insurance Coverage as Payment

A. Proposed Requirement in the NPRM To Treat Proof of Insurance Coverage as Payment and the Basis for Such Proposal

The Eyeglass Rule requires that prescribers provide consumers with a copy of their prescription immediately after the eye examination is completed, but also contains a long-standing 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.[353] The CLR contains a similar provision, permitting the collection of fees for an eye examination, fitting, and evaluation before the release of a contact lens prescription, but also provides clarification that for purposes of this exception, a patient's presentation of proof of insurance coverage for those services shall be deemed to constitute a payment.[354] The Eyeglass Rule does not contain this insurance clarification, and staff has received questions from the public about this issue. The Commission proposed that such a proviso, which was initially formulated by Congress in drafting the FCLCA,[355] 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 and eliminate unnecessary confusion.[356] Accordingly, in the NPRM the Commission proposed to amend § 456.2(a) to add the sentence, ''For purposes of the preceding sentence, the presentation of proof of insurance coverage for that service shall be deemed to be a payment.'' [357] The Commission invited public comment on the potential benefits and burdens of such an amendment.[358]

B. Comments on NPRM and Discussion at Workshop Regarding the Insurance Coverage as Payment Proposal

The Commission received a few public comments addressing this proposed amendment. NAROC supported the Commission's clarification that proof of insurance coverage shall be deemed to constitute a payment under § 456.2(a), and opined that this clarification will generally increase compliance with the Rule's prescription release requirement.[359] 1–800 CONTACTS also supported ''amending the [Rule] to follow the CLR in requiring that prescribers accept proof of insurance coverage as payment for purposes of automatic prescription release.'' [360]

The AAO expressed concern that the provision could create challenges for, and ultimately result in financial impacts to, ophthalmology practices, such as instances where a patient has already utilized their insurance benefit and would thus be ineligible at the time of the visit to be covered by

insurance.[361] Requiring the prescriber to accept proof of insurance as payment in such a situation would be problematic for the prescriber, since the insurance would not be obligated to pay anything. The AAO noted that a ''remedy for this would be to instead allow for insurance to be used as payment if the insurance carrier confirms that the patient is eligible for the benefit at the time of their visit.'' [362] An anonymous commenter stated there can be a problem with vision plans showing authorizations for services but not guaranteeing payment, which takes advantage of the prescriber.[363]

C. Additional Discussion and Commission Determination Regarding the Insurance Coverage as Payment Proposal

The Commission has decided that the proposed clarification in the NPRM's § 456.2(a) will aid prescribers' compliance with the Rule and help ensure that patients and prescribers understand when a prescription should be released. Accordingly, the Commission is adopting the provision as proposed in the NPRM as § 456.2(a)(2). Regarding the AAO's concern that prescribers should be allowed to wait until an insurance carrier confirms a patient's eligibility for a benefit at the time of service, the Commission notes that this is, in fact, what the provision would permit. Section 456.2(a)(2) states that proof of insurance coverage—not merely possession of an optical or health insurance policy—will be deemed to constitute payment. For the anonymous commenter who was concerned about vision plans that show authorizations for services but do not guarantee payment, this prescriber could withhold the prescription pending payment if coverage cannot be conclusively established. But in such a case, the prescriber also could not offer to sell the patient eyeglasses until after releasing the prescription to the patient.[364]

Participants at the workshop discussed that some patients may prefer not to have to make two separate payments—one for the examination fee, prior to receiving the prescription, and a separate one for the purchase of eyeglasses, if they choose to purchase from their prescriber's office.[365] Commission staff noted that the Eyeglass Rule does not mandate when prescribers collect payment for examination fees or eyeglasses, but instead merely requires that the prescription be released immediately after the exam and before offering to sell the patient eyeglasses.[366] Prescribers may decide to wait to collect the examination fee until a purchase is completed, if they believe their patients have a strong preference for a single transaction, so long as they already released the prescription prior to making that sale.[367]

VI. Final Rule Regarding ''Eye Examination'' Terminology

A. Proposed Revision in the NPRM To Change ''Eye Examination'' Term to ''Refractive Eye Examination'' and the Basis for Such Proposal

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.'' [368] As discussed above, 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.[369] In response to the ANPR, the AOA and several individual prescribers requested that the Commission modify the Rule to change the term ''eye examination'' to ''refraction.'' [370] 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.[371] Commenters stated that the Rule should reflect that a comprehensive eye examination and a refraction are separate services,[372] and that while eye health exams are typically covered by Medicare, the testing required to produce the refractive prescription may not be a covered service under Medicare or other insurance plans, and therefore patients may be required to pay out of pocket for the service.[373] The commenters suggested that changing the Rule to reflect the separate services and payments involved would reduce consumer confusion.

In the NPRM, the Commission responded to the ANPR commenters by proposing to replace the term ''eye examination'' with ''refractive eye examination'' throughout the Rule, noting that 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 must be provided free of any additional charge, without obligation, and without a waiver.[374] The Commission opined that 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. The Commission invited further public comment on the potential benefits and burdens of such an amendment; and asked whether the current definition in the Rule is a clear and accurate way of describing a refractive eye examination, whether using the term ''refractive eye examination'' in place of ''eye examination'' could help avoid confusion over when the prescriber must release the prescription, and whether prescribers should be allowed to withhold release of the prescription subject to any charges other than the one due for the refractive eye examination.[375]

B. Comments on NPRM and Discussion at Workshop Regarding the ''Refractive Eye Examination'' Proposal

1. Comments About the Proposed Terminology Change

The FTC received some comments in support of the proposed terminology change. 1–800 CONTACTS agreed with the Commission's proposal to replace the term ''eye examination'' with the term ''refractive eye examination'' throughout the Rule.[376] The National Taxpayers Union asserted that clarifying that an ''examination'' triggering the prescription release requirement is ''one involving a refractive diagnostic . . . should provide some reduction in overhead for providers, who might otherwise spend time and effort explaining to the consumer those conditions under which a prescription is not automatically furnished.'' [377] NAROC stated that it was not aware of compliance concerns arising from the use of the term ''eye examination'' versus ''refractive eye examination,'' and had never heard the complaint that a prescriber did not understand the context of the prescription-release requirement, but acknowledged that the proposed change would eliminate the issues described in the NPRM.[378] NAROC further recognized that prescribers also conduct examinations that are not related to prescribing corrective eyewear, and noted that the proposed change might improve the FTC's ability to enforce the Rule, in that the prescriber would not have the

excuse that they did not understand scope of the term.[379]

While not expressly taking a position on the NPRM proposal to change the terminology, the American Academy of Ophthalmology did express concern—in relation to insurance payments—that many patients are confused as to the difference between health exams that are covered by insurance and refractive exams which often are not.[380] The association said the Commission could be ''more proactive'' in explaining that eye health exams and exams that lead to eyeglass prescriptions are not the same services.[381]

AOA, while in favor of the proposed change in 2015, noted that its position had ''evolved'' since then,[382] and opined that the terminology change ''may not truly address any confusion that exists,'' noting that the results of a refractive examination do not necessarily provide all the information needed to determine and devise an optical prescription.[383] The AOA asked that if the FTC chooses to update the language as proposed, it should clarify that the update does not impact any State or Federal definitions of a comprehensive eye examination.[384]

At the workshop, Dr. Beatty echoed the AOA's concern that consumers benefit most from a comprehensive eye examination, and worried that labeling the exam that results in a prescription a ''refractive exam'' starts to ''confuse patients as to what the value is for having a full eye exam, and can start to make that feel the same as having some exam that you are getting online without the presence of the doctor.'' [385] At the same time, Dr. Beatty confirmed that the definition in the Eyeglass Rule accurately describes a refraction.[386]

2. Comments About the Need To Allow Prescribers To Make a Medical Decision To Withhold the Prescription, Where Appropriate

Commenters also noted that while a refraction may be provided to a patient for the purpose of determining their most current and appropriate eyeglass prescription, it may also be ''completed as a 'diagnostic tool' to assist in the determination of visual status when there are comorbidities in the visual system.'' [387] In this case, the intent of the refraction may not be to create and provide a prescription for eyeglasses or contact lenses, but rather to understand how the patient's refractive error may be a factor in decreased vision, and to help diagnose medical conditions in the eye, such as macular degeneration or a cataract.[388] In the latter scenario, the eye care professional may even determine that it is not appropriate to provide a prescription for corrective eyewear, if the refractive error is not the cause of the decreased vision and comorbidities are present. Commenters felt that the eye care provider should, in their discretion, be free to make the medical decision of whether to dispense the diagnostic refraction, and not be required by the Rule to release a copy of the prescription solely because they had tested the patients' refractive error.[389] Commenters also stated that regardless of whether the provider releases the prescription in that case, they should be able to charge the patient for the diagnostic examination that was completed.[390]

3. Comments About the Permissibility To Charge for the Refraction, as Opposed To Charging for the Prescription Release

Although the Rule allows eye care prescribers to withhold a patient's prescription until the patient has paid for the ''eye examination''—so long as the prescriber would have required immediate payment even if the exam had revealed that no ophthalmic goods were required—the Rule also prohibits prescribers from ''charg[ing] the patient any fee in addition to the ophthalmologist's or optometrist's examination fee as a condition to releasing the prescription to the patient.'' [391] This provision is intended to prevent a once-common practice whereby prescribers would charge their patients a separate fee for releasing the prescription, which could, in turn, dissuade patients from taking their prescription to shop elsewhere for eyeglasses. Some commenters discussed that consumers can be confused about whether a fee is being charged for the exam or for the prescription, and that the Rule language has resulted in some patients believing that they do not have to pay for the refractive exam.[392] Commission staff noted, based on their experience enforcing the Eyeglass Rule, that some practices may tell patients that there is a charge for the prescription, without indicating that the charge is actually for the refractive exam, rather than for receiving the prescription, and that this can lead to consumer confusion about their rights under the Rule.[393]

C. Additional Discussion and Commission Determination Regarding the ''Refractive Eye Examination'' Proposal

After considering all of the comments in the record on the question of the appropriate terminology for the ''eye examination'' definition, the Commission has decided to amend this term to ''refractive eye examination'' throughout the Rule.[394] Both the comments the Commission received in 2015 and the panel discussion at the 2023 workshop confirmed that the definition in the Rule most accurately describes a refraction. A refractive eye examination can be a portion of a more comprehensive exam, but by changing the terminology, the Rule will provide a clear indication to the consumer and prescriber that if the refraction has been completed, the prescription should be provided, barring a medical decision by the prescriber.

By making this change, the Commission is not suggesting that consumers would not benefit from a comprehensive eye examination, or that it would be preferable for consumers to seek out solely a refraction in order to obtain their prescription. But the Commission is aware that a refraction can be completed in a variety of contexts, and wishes to clarify that regardless of the purpose of the examination, the prescription should always be released whenever the optometrist or ophthalmologist determines the patient's refractive error.[395] The Commission is mindful, however, that in some cases in which the refraction may be used as a diagnostic tool, the provider may make a medical decision that it would not be appropriate for a patient to obtain eyeglasses. The Commission does not intend the Rule to override the provider's medical judgment in such cases. If a prescriber determines it is not medically appropriate for the results of a refractive exam to result in a prescription for a particular patient, the prescriber may choose not to release the prescription. But, in such cases, the prescriber may not then offer to sell the patient eyeglasses.[396] Moreover, the prescription should not be withheld merely due to it being inconvenient for the prescriber to provide it.

The Commission concludes that changing the term to ''refractive eye examination'' may help consumers understand that they may be required to pay for the refraction if it is not covered by a vision plan or other health insurance. Furthermore, this terminology change will help prescribers understand that while they may withhold the prescription pending receipt of payment for the refraction, it is not appropriate to make prescription-release contingent upon the payment for any additional service.

The Commission plans to undertake additional consumer education after the Rule is amended to help patients understand that they may be charged for the exam, but not for the prescription

itself. Revised business education materials can also advise prescribers on the types of fees that may be assessed as a condition of prescription release, as well as advise them to train staff to communicate the purpose of fees to patients.

VII. Miscellaneous Issues Raised in Comments

A. Pupillary Distance

1. Background and Comments

In the NPRM, the Commission explored whether to amend the Rule to require the inclusion of pupillary distance on eyeglass prescriptions. Pupillary distance is the measurement (in millimeters) of the distance between the pupils of a person's eyes and is typically needed to properly fit a pair of eyeglasses.[397] The Rule has historically left it to the States to determine what measurements constitute a complete refractive prescription, and thus, it has been up to the States to determine whether pupillary distance is required to be included on prescriptions.[398] In the NPRM, the Commission analyzed comments received in response to the ANPR in favor of and against adding a pupillary distance requirement and concluded that there was not adequate evidence in the rulemaking record at this time to determine that the failure to provide a pupillary distance on a prescription is an unfair practice.[399] As a result, in the NPRM the Commission did not propose to require prescribers to include the pupillary distance measurement on prescriptions.[400] However, since it had last invited comment on the question of whether to require the inclusion of pupillary distance in a prescription in 2015, and the market for optometry and eyeglasses may have evolved since then, the Commission, in the NPRM, again invited comment on this issue. Specifically, the Commission asked for input and information about changes to State regulation on the content of prescriptions, or to changes in the marketplace, or to changes in technology, that might affect and alter the Commission's prior conclusion that pupillary distance on prescriptions should not be required by rule.[401]

In response, the Commission did not receive any comments addressing changes to State regulations on the content of prescriptions, or changes in the marketplace, or changes to technology pertaining to pupillary distance. Commenters in favor of and against the inclusion of pupillary distance on prescriptions largely reiterated viewpoints previously expressed in response to the ANPR.

The Commission received a number of comments in favor of the Commission's NPRM determination not to require the inclusion of pupillary distance on prescriptions from optometry, ophthalmology, and optician trade groups (the AOA, AAO, and OAA, respectively). The AOA, for instance, agreed with the Commission's concern, as discussed in the NPRM, that requiring pupillary distance measurements on prescriptions could place the patient in the optical dispensary—where pupillary distance measuring devices are typically located and operated—prior to the patient receiving their prescription, thereby undercutting the Rule's long-standing principle (a foundation of the Rule) of separating a patient's eye examination from the retail dispensing of eyeglasses. The AOA and the OAA added further that, historically, taking pupillary distance measurements is not a standard part of an eye examination by an optometrist or ophthalmologist (it is typically performed by an optical goods dispenser, such as an optician, in the dispensary *after* a patient decides to purchase glasses), and stated that there was no reason to require that prescriptions from refractive eye exams, written by optometrists and ophthalmologists, should include pupillary distance.[402] The AOA also pointed to Commission language in the NPRM stating that there are zero-cost and relatively-low-cost alternative methods for consumers to obtain their pupillary distance if they wish to shop for glasses online.[403] The trade association NAROC also agreed with the Commission's NPRM determination, stating that if the pupillary distance requirement was added, prescribers and opticians might end up at odds over whose pupillary distance measurement should control.[404]

The OAA further expressed concern that if pupillary distance is required on prescriptions, opticians filling the prescription would have to abide by the exact measurements written on the prescription by the prescriber, regardless of the accuracy of the information or their own measurement, and stated that opticians—who have a long history of performing pupillary distance measuring tests—may consider several factors such as: whether the current pupillary distance measurement matches the previous measurement, changes that may have occurred since the issuance of the prescription, and the complexity of the prescription.[405]

The AAO also agreed with the Commission's decision not to mandate the inclusion of pupillary distance measurements on eyeglass prescriptions.[406] The group said that because many ophthalmologists do not take this measurement, and not all ophthalmic practices have an optician on staff to perform these measurements, if pupillary distance were required on prescriptions, ophthalmologists would be forced to make difficult practice decisions over the hiring of additional staff or the elimination of refractive services.[407]

On the other hand, some sellers and consumers said they would like the Commission to reconsider its decision and require prescribers to include pupillary distance on prescriptions. Online seller Eyeglasses.com stated that it receives hundreds of prescriptions from consumers each day and about half of them do not include the pupillary distance measurement, making it challenging to provide them with eyeglasses.[408] The seller contended that the failure to provide pupillary distance is an obstacle to consumer choice, and expressed its belief that prescribers do not add this measurement because they either do not want to take the extra time to take the measurement, or because such prescribers sell eyeglasses themselves, and withhold the measurement to make it more difficult for consumers to buy eyeglasses elsewhere. According to Eyeglass.com, consumers are frequently too embarrassed to ask for the pupillary distance measurement, and if they do ask the prescriber, it gives the prescriber an opportunity to discourage the patient from buying online or elsewhere. The seller also noted that some prescribers charge a fee to measure the pupillary distance, which is not prohibited by the Rule.[409]

1–800 CONTACTS, which also sells eyeglasses, reiterated the view that not giving consumers their pupillary distance measurement could discourage online shopping and result in diminished competition and less consumer choice.[410] It opined that the elements of unfairness are met when a prescriber's office takes the pupillary distance measurement during the patient's visit but fails to automatically provide that measurement to the patient, and reiterated that patients may not know to ask for their pupillary distance, may not want to offend the prescriber by asking for that measurement, or may be refused or charged for that measurement.[411] According to 1–800 CONTACTS, obtaining the pupillary distance measurement on their own may be a costly or time-consuming hassle for some consumers, and some consumers may not be aware of the ways in which they can obtain their pupillary distance

measurement. Moreover, in response to the Commission's stated concern that a pupillary distance requirement could have the unintended and undesirable consequence of placing the patient in the dispensary prior to them having their prescription in hand, 1–800 CONTACTS proposed that the pupillary distance measurement should be released in some other format, separate from the refractive prescription itself.[412] For this scenario, the commenter explained, the prescriber would release the prescription prior to the patient entering the dispensary, and the patient would then automatically receive their pupillary distance measurement separately after having it measured in the dispensary.[413] 1–800 CONTACTS asserted that an appropriately tailored amendment to automatically release a pupillary distance measurement is critical to creating prescription portability and promoting competition in the evolving market for prescription eyewear.[414]

Another commenter, a consumer, stated that pupillary distance measurements are needed to order glasses online, where glasses are much cheaper than in the optometrist's shop.[415] The commenter said that, when they ask their prescriber for the measurement, the prescriber does not provide it, and instead tells them that the measurement will be taken when they buy eyeglasses. The commenter felt this was a way to force consumers to buy their eyeglasses at their prescriber's office, or at the least, discourage them from buying glasses online.[416]

2. Pupillary Distance Requirement Determination

After considering the comments and evidence regarding pupillary distance, the Commission does not disturb its conclusion, reached in the NPRM and previous Eyeglass Rule rulemakings, not to mandate the inclusion of pupillary distance on prescriptions in States that do not otherwise include such a requirement. To determine 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.[417] The comments submitted in response to the NPRM did not reveal any relevant changes in the marketplace, technology, or State regulations that sufficiently alter the landscape such that not providing a pupillary distance measurement is generally unfair. The comments largely raise the same points as those submitted in response to the ANPR,[418] indicating that requiring the inclusion of pupillary distance measurements on prescriptions could potentially increase consumer convenience and improve competition, but could also impose burdens on prescribers, hamstring opticians, and undercut other pro-competitive aspects of the Rule. On balance, upon review of the record, the Commission finds again that there is not sufficient evidence that the practice of not providing pupillary distance is an unfair act or practice.

Purchasing eyeglasses online can, indeed, be more convenient and less costly for consumers, and consumers can find it more difficult to shop online if their pupillary distance is not provided by prescribers. But every State determines what is required to be included in an eyeglass prescription, and only four require the inclusion of pupillary distance measurements.

Based on the record developed, the Commission concludes that preempting these State determinations by imposing a requirement to include pupillary distance on the prescription may have a detrimental overall effect for prescribers and consumers. Some prescribers—particularly ophthalmologists—would be required to take a measurement they do not ordinarily take, or might feel obligated, for professional and liability reasons, to hire new staff or acquire new equipment to take this measurement, which could result in higher costs passed on to patients in the form of higher prices.[419] Particularly for smaller practices, the costs to these providers could be considerable.

In addition, imposing such a requirement could undermine the pro-competitive aim of the Rule. If the Commission required the inclusion of pupillary distance, some prescribers might lead patients to the dispensary for the measurement, instead of adding expensive pupillary distance measurement equipment to the exam room.[420] As noted above, such a shift would place the patient in the dispensary prior to the patient receiving their prescription, a result that would blur the important distinction between the clinical eye exam and the retail dispensing process, a distinction that is central to the Rule, and that the Commission has consistently attempted to preserve.

Although commenters point to circumstances under which the act of not providing a pupillary distance measurement can be injurious, consumers have alternative means to obtain eyeglasses from a seller other than their prescriber. Other methods are available for consumers to obtain this measurement, and many of these methods—while possibly not as precise as a measurement taken with expensive equipment by an optician in a dispensary—are low-cost or no-cost. For instance, one seller stated that all you need is a mirror and a printable ruler,[421] and another provided instructions for using their digital ruler.[422] Consumers can also obtain this measurement at an in-person optical dispensary, though it may come at a small cost if the consumer is not purchasing eyeglasses at that shop.[423] Although some consumers reported problems with their vision when using eyeglasses made with pupillary distances they measured themselves using online tools,[424] NAROC stated that many online sellers have developed accurate alternative ways to measure pupillary distance.[425] Moreover, a new pupillary distance measurement does not have to be obtained every year or office visit. Obtaining it once is usually sufficient, since for most people, the measurement does not change significantly from one year to the next. The widespread availability of these alternative methods make it difficult to conclude at this time that the injury to consumers from prescribers failing to take and provide pupillary distance measurements is both substantial and not reasonably avoidable.

Importantly, the Commission's determination does not preclude States from defining prescriptions to include pupillary distance measurements. Indeed, in the handful of States that already do so, the Rule, by its operation, requires dispensing of such measurements. But the Commission is mindful that the vast majority of States have not required prescribers to include pupillary distance measurements, and the Commission is reluctant to override the determinations of local jurisdictions without a clearer record establishing that the status quo is unfair.

For these reasons and others described in the Commission's NPRM,[426] the Commission has decided at this time to retain its prior conclusion not to amend the Rule to add a pupillary distance requirement for prescriptions.[427]

B. Consumer and Business Education

Commenters and workshop participants stated that the Commission should better educate consumers about their rights to their prescription, or the confirmation process. Dr. Masoudi stated that consumers should be made more aware of their rights before they walk in the door.[428] This point was illustrated at the workshop by Felecia Neilly, who stated that before she became involved with this Rule review

process, she ''wasn't even aware of an eyeglass rule'' and did not know she had the option to receive the prescription.[429] As to the confirmation requirement, Dr. Montaquila stated that there is widespread confusion by his patients as to why they are signing a prescription.[430] One anonymous commenter stated that the burden should be on the FTC to provide education to the consumer.[431] The AAO added its concern that patients misunderstand that services resulting in a prescription, in addition to the prescription, are to be provided free of charge.[432]

Some commenters also mentioned that in addition to a need to educate consumers, there is a need to educate prescribers about their responsibilities under the Rule. NAROC requested the Commission work with industry to develop useful guidance or templates relating to patients' rights and prescribers' responsibilities with respect to eyewear prescription release.[433]

The Commission has existing guidance on the Eyeglass Rule on its website and has engaged in outreach to both consumers and prescribers at periodic intervals, including through press releases, consumer alerts, and business blogs announcing warning letters to prescribers.[434] Nevertheless, it agrees it should bolster its existing guidance on the Rule as an added measure to inform consumers of their rights, and businesses of their obligations, especially given the amendments to the Rule.

VIII. 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.

In this final rule, the Commission is amending a rule that contains recordkeeping and other collection of information requirements as defined by OMB regulations that implement the PRA. First, the Commission is modifying the Rule to require that: (i) if a paper copy of the prescription was provided to the patient, the prescriber must request that the patient acknowledge receipt of the prescription by signing a separate statement on paper or in a digital format confirming receipt of the prescription, and retain the confirmation for not less than three years; or (ii) if a digital copy of the prescription was provided to the patient (via methods including an online portal, electronic mail, or text message), the prescriber must retain evidence that such prescription was sent, received, or made accessible, downloadable, and printable.[436]

Section 456.4(a)(2) provides sample language for option paragraph (a)(2)(i) in that prescribers may use the single-sentence statement, ''My eye care professional provided me with a copy of my prescription at the completion of my examination,'' but also allows prescribers to craft their own wording of the signed confirmation if they so desire. For prescribers who choose to offer an electronic method of prescription delivery, the Rule will require that such prescribers identify the specific method or methods to be used and maintain records or evidence of affirmative consent by patients to such digital delivery for at least three years. For instances where a consumer refuses to sign the confirmation or accept digital delivery of their prescription, the Rule (§ 456.4(a)(3)) directs the prescriber to note the refusal and preserve this record as evidence of compliance. None of these new requirements, however, would apply to prescribers who do not have a direct or indirect financial interest in the sale of eyeglasses.

Below, the Commission describes and discusses the changes between the proposed rule regulatory text and this final rule, the public comments received relating to the collection of information burden, and the Commission's ultimate determination of the burden generated by the final rule.

A. Comments Regarding the NPRM Estimate for the Confirmation-of-Prescription-Release Requirement

In its NPRM, the Commission put forth estimates for the burden on individual prescribers' offices to generate and present to patients the confirmations of prescription release, and to collect and maintain the confirmations of prescription release for a period of not less than three years. Based on an estimate that there are 165 million eyeglass wearers in the United States, the Commission calculated the total disclosure and recordkeeping burden from the new requirement at 2,979,167 hours for prescribers and their staff (1,375,000 disclosure hours + 1,604,167 recordkeeping hours).[437] These totals were based on estimates that it would take prescribers' offices one minute to hand out a prescription, ten seconds for the patients to read and sign a confirmation-of-prescription-release statement or consent-to-electronic-prescription-delivery, and one minute for prescribers' offices to store (or scan and save) the signed confirmation or consent in their files.[438] The Commission's time estimates were based on previously-approved estimates for a nearly identical confirmation-of-prescription-release requirement added to the Contact Lens Rule in 2020.[439]

In its NPRM, the Commission requested comment on, among other things, the accuracy of the FTC's burden estimates, including whether the methodology and assumptions used were valid.[440] In response, the Commission received various comments from prescribers opining, among other things, that a confirmation requirement for eyeglass prescriptions would ''take an immense amount of time and take away from patient care,'' [441] be ''very time consuming,'' [442] and ''add a significant burden to small business optometry practices that already are enduring financial challenges and staffing issues.'' [443] More specifically, some commenters, such as the American Optometric Association and Eyeglass workshop panelist Dr. Jeffrey Michaels stated that the Commission had previously underestimated the time it takes to perform the confirmation requirement,[444] and commenter Coast Eyes Pllc suggested the paperwork cost would be $18,000 per provider per year.[445] Another workshop panelist, Dr. Stephen Montaquila concurred with Dr. Michaels, commenting that it takes his staff four minutes to complete the entire Contact Lens Rule process of printing out a patient's prescription, handing it to the patient, explaining why it needs to be signed, having the patient sign it, making a copy of it, and storing the signed copy as a record.[446] In addition, the National Taxpayers Union submitted a comment stating that while it generally supports the confirmation requirement, ''[G]iven the various reading speeds of customers who may be elderly or have limited proficiency in English, the 10-second estimate [to read and sign the statement] could prove low.'' [447] As noted previously in the discussion of the proposed confirmation requirement, the NTU also suggested that smaller optometry practices might bear a disproportionate share of the burden, which it estimated—based on the NPRM proposal and the estimate that that a ''modest optometry establishment'' might perform 3000 examinations per year—at an additional 167 hours and $4,123 per year for such an establishment.[448]

Some commenters, however, disagreed that it would take a significant amount of time to obtain a patient's signed confirmation. The NAROC commented that thousands of optometrists affiliated in co-location with NAROC member companies ''regularly comply with [Contact Lens Rule confirmation-of-prescription-release requirements, as well as other requirements of the CLR and Eyeglass Rule] with little or no added cost or other burden on the eye care practice.'' [449] According to NAROC representative and Eyeglass Rule workshop panelist Joseph Neville, ''I've personally witnessed a couple of situations where the process for contact lenses seemed very easy. . . . the prescription was handed over at the front desk by the staff person, and the staff person maybe a bit simplistically said, 'We'd like to ask you to sign this receipt for your prescription. We're required to get your signature acknowledging that you've received it.' And a couple of people, and again, anecdotes here that I witnessed on this, just said, 'Okay, fine, thank you.' '' [450]

All of the above comments, however, are, as Mr. Neville acknowledged, anecdotal in nature.[451] The only new empirical evidence that the Commission is aware of regarding the time it will take prescribers and their staff to comply with a confirmation-of-prescription-release requirement comes from an American Optometric Association submission filed in response to a 2023 request for comment about extending Office of Management and Budget (''OMB'') clearance for the information collection requirements of the Contact Lens Rule.[452] In that submission, the AOA said that the Commission ''significantly underestimated'' how long it would take prescribers to confirm prescription release for the Contact Lens Rule requirement, and cited a 2023 survey it conducted of some of its member optometrists which found that 84.8% report it takes 30 seconds or more to obtain the patient's signed confirmation for contact lens prescriptions, not counting additional time necessary to address patient questions about the form they are signing, and 69.9% of prescribers said patients ''typically'' have questions regarding the acknowledgment.[453] Since the confirmation-of-prescription-release requirement adopted herein is very similar to that for the Contact Lens Rule, the Commission regards AOA's comment regarding the CLR's burden as on point.

The Commission cannot, however, accord the AOA survey significant weight. As explained in the Commission's notice responding to public comments on extending OMB's approval for CLR collection of information for another three years,[454] it is very likely the AOA survey overestimates the average time necessary to obtain a confirmation because of the manner in which the survey solicited prescribers to respond. AOA emailed a newsletter to members and included an invitation to ''Voice your concerns'' about complying with the Contact Lens Rule. A small number of prescribers self-selected in response, and took part in the survey. Because the poll only included prescribers who responded to this invitation, it is questionable whether its findings are truly representative of the average prescriber.[455] Furthermore, framing the survey as an invitation for concerned prescribers to air their grievances rather than as a disinterested information-gathering tool affects the objective reliability of survey responses, making it much harder for the Commission to accord it significant weight.

The Commission also reiterates concerns—previously detailed in the Commission's CLR PRA Notice [456]—that the amount of time prescribers ascribe to patients reading and signing that Rule's confirmation statement may, in fact, be due largely to non-mandated choices with respect to the design of the statement. The Contact Lens Rule requires that patients read and sign a simple statement confirming receipt of their prescription, and allows that the one-sentence statement, ''My eye care professional provided me with a copy of my contact lens prescription at the completion of my contact lens fitting,'' fully satisfies the requirement. However, the Contact Lens Rule also permits prescribers to design their own confirmation form and statement, and the survey did not specify or ask prescribers what form or wording of the confirmation statement that patients were reading and signing, making it difficult to determine a true average time it would take to comply with the requirements of the rule. Even more concerning (from the standpoint of assessing the burden) is that the AOA has supplied its members with a model template confirmation form that includes several additional paragraphs consisting of ''important information to review prior to receiving your contact lens prescription.'' [457] This information includes various recommendations from the Centers for Disease Control (''CDC'') and the Food and Drug Administration (''FDA'') about healthy contact lens use (such as ''Take out your contacts and call your eye doctor if you have eye pain, discomfort, redness, or blurry vision'') as well as five bullet points listing some of the symptoms for an eye infection (''Irritated, red eyes, worsening pain in or around the eyes,'' etc.).[458] While the template document is titled ''Contact Lens Prescription Acknowledgment Form,'' only at the very end is there a statement, ''Sign below to acknowledge that you were provided a copy of your contact lens prescription at the completion of your contact lens fitting.'' [459]

According to workshop panelist Dr. Montaquila, the AOA template is a common form that eye doctors are using to obtain patient confirmations.[460] If this is indeed the case, it calls into question the relevance of AOA's survey results finding that it takes patients 30 seconds or longer to comply with the Contact Lens Rule requirements, since the majority of those 30 seconds would likely be taken up by patients reading information that the rule does *not* require, or even suggest, that they read. Widespread use of AOA's model template confirmation form might also account for why prescribers report that patients have questions, or are confused, as to why they need to sign a new form, since patients are being asked not merely to confirm they received their prescription, but that they received other information from the CDC and FDA.[461] While the additional information from these two Federal agencies may very well be useful to provide to patients, it is not required by the FTC, and the time it takes patients to read it is not part of the Rule's burden of compliance.

Despite the aforementioned concerns about the reliability of the AOA's survey in establishing the time it takes for a patient confirmation, the Commission does not wholly discount the survey, but rather views it as suggestive, and an additional indication that many prescribers sincerely believe the Commission's 10-second estimate does not accurately reflect the time required to obtain a patient's signed confirmation. The Commission has therefore decided to increase its estimate for the time required to obtain a patient confirmation signature (and the time to collect an affirmative consent to electronic delivery, in instances where the prescription is provided digitally rather than in paper) for the Eyeglass Rule from 10 seconds—as proposed in the NPRM—to 20 seconds for this final rule. The Commission concludes that 20 seconds may better reflect the time required for a patient to not just read a one-sentence confirmation, but also to physically sign

and return the document to prescriber's staff, and for any necessary staff explanation as to why the patient's signature is required.[462] The 20-second estimate may also better align with the original HIPAA estimate that was a basis for the initial CLR confirmation estimate, since the original HIPAA proposal accorded 10 seconds to hand out the acknowledgment and another 10 seconds to obtain a patient's signature and collect the document.[463]

The Commission hereby provides PRA burden estimates, analysis, and discussion for the existing Eyeglass Rule burden of automatically releasing a prescription at the completion of a refractive eye exam, as well as the new requirement to collect patient signatures as confirmation of prescription release or as consent to electronic prescription delivery. The Commission estimates these PRA burdens based on the comments and submissions discussed above, in conjunction with its long-standing knowledge and experience with the eye care industry. The Commission is submitting these amendments and a Supporting Statement to OMB for review.

B. Commission Estimate of the Total Burden = 3,208,333 Hours

1. Estimated Hour Burden of 1,375,000 Hours for Prescribers To Release Prescriptions

The number of adult eyeglass wearers in the United States is currently estimated to be approximately 165 million.[464] Assuming a biennial refractive eyeglass exam for each eyeglass wearer,[465] 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.[466] It is possible that one minute is an overestimate of the amount of time required, particularly as more doctors move to digital delivery. As of now, however, we have not seen sufficient evidence to merit making a change to the approach we have taken in the past. We therefore estimate an annual disclosure burden for prescribers to formulate and release prescriptions of approximately 1,375,000 hours (82.5 million annual exams × 1 min/60 mins).

2. Estimated Hour Burden of Prescribers' Staff To Obtain and Store Patient Confirmation of Prescription Release = 1,375,000 Hours (343,750 Hours for Patients To Read and Sign Confirmations, 1,031,250 Hours for Prescribers' Offices To Scan and Store Such Confirmations)

The requirement to generate and present the confirmation of prescription release will not require significant time or effort. The requirement is flexible in that it allows different modalities and delivery methods at the discretion of the prescriber. The requirement is also flexible in that it does not dictate other details, such as the precise content or language of the patient confirmation. At the same time, prescribers and their staff would not be obligated to spend time formulating their own content for the confirmation, since the amended Rule provides draft language that prescribers are free to use, should they so desire. Furthermore, prescribers likely have forms and systems in place to maintain confirmation records already, since they already must comply with the similar confirmation requirement of the Contact Lens Rule, and may need make only minor adjustments to accommodate confirmations for eyeglasses prescriptions. As a result, the marginal cost of the Confirmation amendment to the Eyeglass Rule should be extremely low, possibly lower than that estimated herein.

As noted above, the requirement of § 456.4(a)(1)(i) to collect a patient's signature on the confirmation of prescription release and preserve it constitutes a new information collection as defined by OMB regulations that implement the PRA. Nonetheless, the Commission determines it will require minimal time for a patient to read the confirmation and provide a signature. As noted above, the Commission estimated in the Contact Lens Rule and the NPRM that it would take patients 10 seconds to read the one-sentence confirmation of prescription release and provide a signature.[467] However, for the reasons discussed above, the Commission now believes that 20 seconds is an appropriate estimate for this task.[468]

The second option, § 456.4(a)(1)(ii), involves digital delivery of the prescription and 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.[469]

In its NPRM, the Commission assumed that prescribers would elect digital prescription delivery 25% of the time, and thus would be required to obtain a signed confirmation for the other 75% of patients receiving prescriptions.[470] That assumption was based on the premise that the NPRM offered prescribers four options (confirmation on a stand-alone document, confirmation on a prescription copy, confirmation on a sales receipt, or digital delivery with no confirmation required). With no specific details that clearly show which option prescribers would prefer, the Commission employed the assumption that prescribers would choose each of four options in equal numbers.

The current Rule amendment has only two options, paper delivery or digital delivery, and thus if the Commission used the same equal-share assumption it followed in the NPRM, the percentage attributed to digital delivery (and thereby not implicating the burden of a confirmation) for PRA purposes would be 50%. However, based on conversations with prescribers and the industry, the Commission has reason to believe that regardless of widespread EHR adoption, many prescribers still do not provide patient portals or deliver prescriptions digitally to patients, and thus it would not be correct to designate 50% of all prescription releases as digital delivery. Further supporting this view, the aforementioned AOA survey found that only 35% of prescribers said they provided prescriptions electronically.[471] Even that might overcount the number of prescriptions delivered digitally, since the prescribers surveyed by AOA about their method for either obtaining patient confirmations and delivering prescriptions were permitted to select more than one option, so some of the 35% who chose digital delivery of prescription (and thus no confirmation) may also have responded that they use other options, meaning that the overall percentage of prescriptions released electronically is actually less than 35%.[472] Furthermore, as discussed above, there are questions as to the reliability of AOA's survey findings, and whether they are truly representative of the average prescriber. Therefore, in order to ensure that the PRA burden for the Rule is not underestimated, the Commission will retain the previously used assumption that just 25% of prescribers employ digital-prescription delivery, and the other 75% of approximately 82.5 million annual prescription releases require a consumer reading and signing a confirmation statement. Thus, assuming twenty seconds for each such release, prescribers' offices would devote

343,750 hours, cumulatively (75% × 82.5 million prescriptions yearly × 20 seconds each/60 secs/60 mins) to obtaining patient signatures as confirmations of prescription release.[473]

Maintaining those signed confirmations for a period of not less than three years should not impose substantial new burdens on individual prescribers and office staff. Since the Rule allows flexibility in how prescribers craft the confirmation statement, prescribers may add it to documents that they would already be saving, such as prescription copies (and the majority of States already require that optometrists keep records of eye examinations for at least three years[474]) or customer sales receipts (which are normally preserved for financial accounting and recordkeeping purposes). Even if the prescriber chooses to create and use a separate confirmation statement, 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, however, the recordkeeping requirement would likely require that office staff electronically scan the signed confirmation and save it as a digital document. For prescribers who preserve the confirmation by scanning it, Commission staff estimates that preserving such a document would consume approximately one minute of staff time.

The Commission does not possess information on the percentage of prescribers' offices that currently use and maintain paper records versus electronic records, or that scan paper files and maintain them electronically. Thus, for purposes of this PRA analysis, and to again guard against possibly underestimating the Rule's burden, the Commission will assume that all prescriber offices who opt for § 456.4(a)(1)(i) (who do not dispense prescriptions electronically) require a full minute per confirmation statement for storing such recordkeeping.

Assuming—as the Commission did above—that 25% of prescriptions will be delivered electronically, and thus 75% of prescriptions require a patient confirmation that must be scanned and saved, the recordkeeping burden for all prescribers' offices to scan and save such confirmations amounts to 1,031,250 hours (75% × 82.5 million prescriptions yearly × one minute for scanning and storing/60 mins) per year.

3. Estimated Hour Burden on Prescribers' Offices To Obtain and Store Patient Consents to Electronic Delivery = 458,333 Hours (114,583 Hours To Obtain Signed Consents and 343,750 Hours To Store Same)

As noted previously, § 456.4(a)(1)(ii), the second option for satisfying the confirmation-of-prescription-release requirement, involves digital delivery of prescriptions, and thus does not necessitate that prescribers obtain or maintain a record of the patient's signature confirming receipt of a prescription. However, this option does require that prescribers obtain and maintain records or evidence of the patients' affirmative consent to electronic delivery for three years. Based on the previous estimate that 25% of patients will receive digital delivery of their prescriptions, the Commission will use the assumption that consumers sign such consents for electronic delivery for one quarter of the 82.5 million prescriptions released per year,[475] and that this task would take the same amount of time as to obtain and preserve a signature of the patient's confirmation of prescription release. Thus, the Commission will assign 114,583 hours for the time required for prescribers' offices to obtain patients' affirmative consent to electronic delivery of their prescriptions[476] and 343,750 hours for the time to store and maintain such records.[477]

In total, the estimated incremental PRA recordkeeping burden for prescribers and their staff resulting from adding the confirmation-of-prescription-release requirement to the Rule amounts to 1,833,333 total hours (343,750 and 114,583 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) for prescribers' offices. Adding this incremental PRA burden to the 1,375,000-hours burden resulting from the existing prescription-release requirement yields a total PRA disclosure and recordkeeping burden from the Rule of 3,208,333 hours for prescribers and their staff.

C. Estimated Labor Cost

The Commission derives labor costs by applying appropriate hourly-cost figures to the burden hours described above. Since prescribers conduct patient examinations and formulate the prescriptions, the time spent releasing prescriptions to patients has traditionally been attributed for PRA purposes to prescribers, rather than their office staff. As for the task of obtaining patient confirmations and consent to electronic delivery, this could be performed by prescribers or their support staff. In the past, the task of collecting patient signatures was attributed to prescribers, but based on more recent conversations with prescribers and others in the industry, it has become evident that this task is more appropriately designated as performed by prescribers' office staff.[478] Therefore, the Commission will continue to assume that prescribers release prescriptions to patients, but that prescribers' office staff perform the task of collecting patient signatures on confirmations and digital-release consents, as well as the labor pertaining to printing, scanning, and storing of both documents.

According to the U.S. Bureau of Labor Statistics (''BLS''), general office clerks earn an average wage of $20.94 per hour, optometrists earn an average wage of $68.75 per hour, and ophthalmologists—which are listed by BLS under ''surgeons''—earn an average wage of $150.06 per hour.[479] Using the average wage for office clerks, and the aforementioned estimate of 1,833,333 total hours for office staff to obtain signed patient confirmations and consents to digital prescription delivery and to store such documents, the Commission calculates an incremental burden of $38,389,993 from adding the confirmation of prescription release to the Eyeglass Rule.[480]

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

Adding the $38,389,993 staff burden from the confirmation-of-prescription-release requirement to the $111,301,438 prescriber burden from the automatic prescription-release requirement already in place yields a total estimated annual labor cost burden for the Eyeglass Rule of $149,691,431. While not insubstantial, this amount constitutes less than one half of one percent of the estimated $35.6 billion retail market for eyeglass sales in the United States in 2022.[481] Furthermore, the actual burden

is likely to be less, because, as noted *supra,* prescribers who do not have a financial interest in the sale of eyewear will not be required to obtain patient confirmations, many prescribers' offices will require less than a minute to store the confirmation form, prescribers can use the same document to obtain confirmations for eyeglass prescriptions and contact lens prescriptions, and, as digital prescription delivery increases over time, the overall burden should correspondingly decrease.

D. Capital and Other Non-Labor Costs

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

IX. Final Regulatory Analysis and Regulatory Flexibility Act Analysis

Under section 22 of the FTC Act, 15 U.S.C. 57b–3, the Commission must issue a final regulatory analysis related to a final 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 amendments will cause a substantial change in the cost or price of certain categories of goods or services; or (3) otherwise determines that the amendments will have a significant effect upon covered entities and upon consumers. The Commission has determined that this final rule will not have such an annual effect on the national economy, on the cost or prices of goods or services, or on covered businesses or consumers.

The amendments adopted in this final rule require that prescribers obtain from patients, and maintain for a period of no less than three years, a signed confirmation of prescription release acknowledging that patients received their eyeglass prescriptions at the completion of their eye examination. The amendments also require some prescribers to obtain and maintain for three years a patient's consent to deliver prescriptions electronically, but only for prescribers who elect to offer this method of delivery as an alternative to providing prescriptions in paper, and only if the patient agrees.

As discussed in the Paperwork Reduction Act section of this document, the Commission approximates that collecting a patient's signature on the confirmation of prescription release (giving time for the patient to read the confirmation) in accordance with § 456.4 will take approximately 20 seconds. Providing the patient with the confirmation of prescription release in accordance with this provision will require prescribers' offices to present a statement of prescription release and request a patient signature. The amendment provides prescribers with language that they can use on a confirmation form, which will relieve prescribers of the burden of coming up with such language. This requirement may also involve some staff training, which should be minimal, particularly since prescribers' staff will already be trained in obtaining patient confirmation of prescription releases under the Contact Lens Rule.[482] As a result, complying with § 456.4(a) will impose only minimal incremental costs on prescribers' offices.[483]

The PRA section of this document also addresses the burden under § 456.4(b) for prescribers to maintain, for at least three years, records confirming their patients' receipt of prescriptions, and estimates it will take one minute for prescribers' staff to meet their recordkeeping obligations. This likely overstates the recordkeeping burden, since, as noted above, 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. Prescribers who decide to collect or maintain signatures electronically may already have electronic health records in place. 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.

As further noted in the Paperwork Reduction Act section of this final rule, the estimated cost to prescribers of complying with all of the requirements of the Eyeglass Rule is just .0042 of the total retail market for prescription eyeglass sales, with the cost of this final rule representing less than a third of that amount. In sum, the burdens imposed on small entities are likely to be relatively small.

The Regulatory Flexibility Act (''RFA''), 5 U.S.C. 601–612, requires an agency to provide an Initial Regulatory Flexibility Analysis (''IRFA'') with a proposed rule and a Final Regulatory Flexibility Act (''FRFA'') with the final rule, if any, unless the agency certifies that the rule will not have a significant impact on a substantial number of small entities.

In the NPRM, the Commission determined the proposed amendments should not have a significant or disproportionate impact on prescribers' costs, and based on available information, the Commission certified that amending the Rule as proposed in the NPRM, would not have a significant impact on a substantial number of small entities. Nonetheless, the Commission determined that it was appropriate to publish an IRFA to inquire into the impact of the proposed rule on small entities. Based on the IRFA set forth in the Commission's NPRM, a review of the public comments submitted in response to that notice and the workshop notice, and the discussions from the Workshop itself, the Commission submits this FRFA. This document serves as notice to the Small Business Administration of the agency's certification of no significant impact.

A. Need for and Objectives of the Final Rule

The Commission has concluded that millions of American consumers in need of corrective vision wear are not receiving their eyeglass prescriptions after visiting their prescriber. It has also concluded that a rulemaking to add a confirmation-of-prescription-release requirement is necessary to increase the number of patients who receive their prescriptions, to inform patients of the Rule and of their right to their prescriptions, and to ensure the separation of eye examination and eyeglass dispensing, which fosters a competitive marketplace for eyeglasses. The Commission notes that prescribers who currently comply with the automatic-release provision of the Rule may presently face a competitive disadvantage because of widespread non-compliance by other prescribers. This creates an unlevel playing field and undermines fair competition. In addition, the Commission expects that this final rule will: 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 prescribers and consumers; and bring the Eyeglass Rule into congruence with the confirmation-of-prescription-release requirements of the Contact Lens Rule, reducing confusion for prescribers and consumers, and easing compliance and enforcement for both rules.

B. Significant Issues Raised by Public Comments in Response to the IRFA and the Agency's Response, Including Any Changes Made in the Final Rule

In crafting the final rule, the Commission carefully considered the comments received throughout the Rule

review process. This document contains a detailed discussion of the comments received by the Commission and the Commission's response to those comments. The Commission did not receive any comment from the Chief Counsel for Advocacy of the Small Business Administration.

The Commission received 47 comments in response to the NPRM and Workshop notices. Some of the comments, from prescribers and prescriber groups, strongly opposed the confirmation-of-prescription-release requirement indicating that such a change was not needed or would be burdensome to comply with. Specifically, those commenters stated that there was not a compliance problem with the Eyeglass Rule's automatic-release provision and the confirmation requirement was therefore an attempt to ''fix something that was not broken.'' Some also commented that the Rule changes, if finalized, would add a burden to small business optometry practices that already are enduring financial challenges and staffing issues. A few commenters contended that compliance with the proposed amendments would take longer than the Commission estimated in its NPRM, as demonstrated by the amount of time it currently takes prescribers to comply with the existing Contact Lens Rule requirements that are similar to those proposed for the Eyeglass Rule.

In contrast to the position expressed above, commenters from NAROC said that it is their understanding—based on responses from their prescriber members—that compliance with the current Contact Lens Rule confirmation-of-prescription-release requirement is occurring with little or no disruption or expense.[484] And as explained in the PRA section of this document, the Commission has concerns about the reliability of some of the evidence, cited by those critical of the Rule's confirmation proposal, as to the burden of the existing contact lens confirmation requirement. The Commission did not ignore or dismiss any comments and evidence outright, however, and evaluated the evidentiary record as a whole in making a final determination.

The Commission is sensitive to the additional burden or cost that this final rule imposes on businesses. However, after weighing all of the comments and evidence, it finds that this final rule will provide many benefits with a relatively small burden or cost. In particular, the Commission determines that the potential benefit of increasing the number of patients in possession of their eyeglass prescriptions is substantial: namely, increased flexibility and choice for consumers; increased competition among eyeglass sellers; 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 Commission concludes that revising the existing remedy of automatic prescription release by adding the confirmation-of-prescription-release mechanism is necessary and beneficial due to demonstrated failures of prescribers to comply with the automatic-release remedy, and to ensure the separation of eye examination and eyeglass dispensing, which engenders a competitive marketplace for eyeglasses. As a result, this final rule adopts the amendments proposed in the NPRM with the modifications discussed in this document.

In response to comments that the Commission, in its NPRM, underestimated the amount of time it takes to comply with the CLR confirmation-of-prescription-release requirements, and for other reasons noted in the PRA section of this document, the Commission increased its time estimate for complying with the new requirements.[485]

C. Description and Estimate of the Number of Small Entities to Which the Amendments Will Apply or Explanation Why No Estimate Is Available

This final rule applies to eyeglass prescribers, and many prescribers will fall into the category of small entities (*e.g.,* offices of optometrists with $9 million or less in annual receipts).[486] 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. In the NPRM, the Commission sought comment on the number or nature of small business entities for which the proposed amendments would have a significant impact.[487] In response, the AOA commented that ''doctors of optometry reported collecting $826,612, on average, in gross receipts in 2021.'' The AOA also stated that 91.9% of optometry practices have fewer than 25 employees.[488] Based on the AOA comment, and staff's knowledge of the eye care industry, including meetings with industry members and a review of industry publications, staff expects that a substantial number of these entities likely qualify as small businesses.[489]

D. Description of the Projected Reporting, Recordkeeping and Other Compliance Requirements of the Amendments, Including an Estimate of the Classes of Small Entities That Will Be Subject to the Requirement and the Type of Professional Skills That Will Be Necessary To Comply

The final rule will impose a confirmation-of-prescription-release requirement on all optometrists or ophthalmologists who have a direct or indirect financial interest in the sale of eyewear. If a paper copy of the prescription was provided to the patient, the prescriber must request that the patient acknowledge receipt of the prescription by signing a separate statement on paper or in a digital format confirming receipt of the prescription. If a digital copy of the prescription was provided to the patient, the prescriber must retain evidence that such prescription was sent, received or made accessible, downloadable, and printable. Prescribers are required to maintain the records or evidence associated with the confirmation of prescription release, or digital delivery of the prescription for at least three years. In addition, if a prescriber elects to provide a digital copy of the prescription to comply with the Rule, the prescriber is required to identify to the patient the specific method or methods of electronic delivery that they will use and to obtain the patient's verifiable affirmative consent to receive a digital copy through the identified method or methods. The prescriber must maintain records or evidence of the patient's affirmative consent for at least three years.

As discussed in section C of section IX., Final Regulatory Analysis and Regulatory Flexibility Act Analysis, we assume that many of the estimated 43,000 active optometrists and 18,000 active ophthalmologists fall within the definition of a small entity. As discussed in the PRA section of this document, we estimate that prescribers' office staff perform the task of collecting patient signatures on confirmations and digital-release consents, as well as the labor pertaining to printing, scanning, and storing of both documents. Prescribers' offices will have to train staff on, and set up procedures for complying with, the new requirements of the Eyeglass Rule. However, as discussed in the PRA section of this document, prescribers likely have forms and systems in place to maintain confirmation records already, since they already must comply with the similar confirmation requirement of the Contact

Lens Rule, and may need make only minor adjustments to accommodate confirmations for eyeglasses prescriptions.

E. Steps Taken To Minimize the Significant Impact, if Any, of the Amendments, Including Why Any Significant Alternatives Were Not Adopted

Commenters at the ANPR stage recommended, as alternatives to the signed acknowledgment proposal, conspicuous signage declaring consumers' right to a copy of their prescription, or an eye care patients' bill of rights notifying consumers of their rights under the Rule. As explained in the NPRM, 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.[490] As explained in the NPRM, the Commission also decided against another proposed alternative, an eye care patients' bill of rights, for reasons including that the bill of rights proposal does not require the type of prescriber recordkeeping that would allow for better Rule monitoring and enforcement, and would not help resolve disputes between patients and prescribers over whether a prescription had been released.[491]

In an attempt to minimize the burdens associated with the confirmation-of-prescription-release requirement, the Rule provides prescribers with different compliance options depending on whether they release a paper or digital copy of the prescription, and provides one-sentence sample language that prescribers can elect to use should they release paper copies of prescriptions. Moreover, this amendment aligns with the prescription-release-related provisions of the Contact Lens Rule, thereby reducing the confusion and complexity that might arise for consumers and prescribers from having different confirmation-of-prescription-release requirements for contact lens and eyeglass prescriptions. In addition, the marginal cost of the amendment to the Eyeglass Rule should be relatively low because the Contact Lens Rule already requires prescribers to obtain confirmation of prescription release and to maintain records of such. Some prescribers likely have forms and systems in place already, which may need only minor adjustments to accommodate confirmations for eyeglass prescriptions.

The Commission also adopts the proposed exemption to the confirmation-of-prescription-release requirements for prescribers who do not have a direct or indirect financial interest in the sale of eyeglasses as § 456.4(c).[492] The purpose of such an exemption is to reduce the burden on prescribers who do not sell lenses.

X. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this final rule as not a ''major rule,'' as defined by 5 U.S.C. 804(2).

List of Subjects in 16 CFR Part 456

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

For the reasons stated in the preamble, the Federal Trade Commission amends 16 CFR part 456 as follows:

PART 456—OPHTHALMIC PRACTICE RULES (EYEGLASS RULE)

■ 1. The authority citation for part 456 is revised to read as follows:

Authority: 15 U.S.C. 57a.

■ 2. Amend § 456.1 by revising paragraphs (a), (b), (d), (e) and (g) 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.

■ 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)(1) Fail to provide to the patient one copy of the patient's prescription immediately after the refractive eye examination is completed and before offering to sell the patient ophthalmic goods, whether or not the prescription is requested by the patient. Such prescription shall be provided:

(i) On paper; or

(ii) In a digital format that can be accessed, downloaded, and printed by the patient, after obtaining verifiable affirmative consent, pursuant to § 456.3.

(2) 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.

§§ 456.3 through 456.5 [Redesignated as §§ 456.5 through 456.7]

■ 4. Redesignate §§ 456.3 through 456.5 as §§ 456.5 through 456.7, respectively.

■ 5. Add new § 456.3 to read as follows:

§ 456.3 Verifiable affirmative consent to providing the prescription in a digital format.

For a prescription copy provided in a digital format, the prescriber shall:

(a) Identify to the patient the specific method or methods of electronic delivery that will be used, such as text message, electronic mail, or an online patient portal;

(b) Obtain, on paper or in a digital format, the patient's verifiable affirmative consent to receive a digital

copy through the identified method or methods; and

(c) 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.

■ 6. Add new § 456.4 to read as follows:

§ 456.4 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) If a paper copy of the prescription was provided to the patient, request that the patient acknowledge receipt of the prescription by signing a separate statement on paper or in a digital format confirming receipt of the prescription; or

(ii) If a digital copy of the prescription was provided to the patient (via methods including an online portal, electronic mail, or text message, and pursuant to § 456.3), retain evidence that such prescription was sent, received, or made accessible, downloadable, and printable.

(2) If the prescriber elects to confirm prescription release via paragraph (a)(1)(i) 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 paragraph (a)(1)(i) 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.

* * * * *

By direction of the Commission.

April J. Tabor,

Secretary.

Endnotes

[1] 16 CFR 456.2(a). A prescriber may withhold a patient's prescription until the patient has paid for the eye examination, but only if the prescriber would have required immediate payment if the examination had revealed that no ophthalmic goods were needed. *Id.* 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.'' 16 CFR 456.1. The Commission is changing this term in the final rule text to ''refractive eye examination,'' in order to make it more precise, and differentiate between eye health exams and refractive exams. *See infra* section VI, Final Rule Regarding ''Eye Examination'' Terminology. However, the meaning of the defined term remains the same, and since it has previously been referred to as ''eye exam'' or ''eye examination''—including by commenters—it is frequently referred to as such throughout the SBP.

[2] 16 CFR 456.2(c).

[3] 16 CFR 456.1(g).

[4] 16 CFR 456.2(b). 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).

[6] 16 CFR 456.2.

[7] 16 CFR part 192 (rescinded); *see also* ''Staff Report on Advertising of Ophthalmic Goods and Services and Proposed Trade Regulation Rule,'' at 235–36 (May 1977), *https://www.ftc.gov/reports/staff-report-advertising-ophthalmic-goods-services-proposed-trade-regulation-rule-16-cfr-part-456* [hereinafter Eyeglass I Report].

[8] *See* Eyeglass I Report, *supra* note 7, at 240–48 (detailing myriad accounts of prescribers refusing to release eyeglass prescriptions to their patients); *see also* Final Trade Regulation Rule, Advertising of Ophthalmic Goods and Services, 43 FR 23992, 23998 (June 2, 1978) [hereinafter Eyeglass I Rule] (finding that in nearly every survey of practicing optometrists considered in the rulemaking record, more than 50% imposed a restriction on the availability of eyeglass prescriptions to patients).

[9] Eyeglass I Rule, 43 FR 23998, 24007–08.

[10] *Id.* at 24003.

[11] *Id.*

[12] *Id.* at 23998.

[13] *Am. Optometric Ass'n* v. *FTC,* 626 F.2d 896, 915 (D.C. Cir. 1980). The Court held that the harm arose by making comparison-shopping harder, removing seller incentives to advertise, and reducing opticians' ability to compete. The Court overturned other provisions of the Rule related to bans on State advertising restrictions. *Id.* at 910–11.

[14] *Id.* at 916. Following the court's remand, FTC staff conducted additional investigation and recommended the Commission seek new comment on whether to keep the automatic-prescription-release requirement or change it to release-upon-request. Fed. Trade Comm'n, State Restrictions on Vision Care Providers: The Effects on Consumers (1980), *https://www.ftc.gov/reports/state-restrictions-vision-care-providers-effects-consumers-eyeglasses-ii.* The Commission then sponsored a survey—commonly known as the ''Market Facts Study''—to determine to what extent prescribers were complying with the Rule. The Study found that only a little more than one-third of prescribers were in ''technical compliance'' with the Rule's prescription-release requirement, and only 38% of consumers knew they were entitled to automatically receive their prescription. *See* Fed. Trade Comm'n, Ophthalmic Practice Rules: State Restrictions on Commercial Practice at 256–58 (Oct. 1986), *https://www.ftc.gov/reports/ophthalmic-practice-rules-state-restrictions-commercial-practice-eyeglasses-ii-report-staff* [hereinafter Eyeglass II Report]. Following the Market Facts Study, the Commission did not take any action to revise the Rule.

[15] Eyeglass II Report, *supra* note 14, at 249.

[16] *Id.* at 249, 274–76.

[17] Eyeglass I Rule, 43 FR 23992, 23998.

[18] Eyeglass II Report, *supra* note 14, at 275–76.

[19] Report of the Presiding Officer on Proposed Trade Regulation Rule: Ophthalmic Practice Rules, Public Record No. 215–63 (1986), *https://www.ftc.gov/reports/report-presiding-officer-proposed-trade-regulation-rule-ophthalmic-practice-rules-eyeglass-rule-16* [hereinafter Presiding Officer's Report].

[20] Eyeglass II Rule, 54 FR 10285, 10286–87. In addition to relying on the Market Facts Study, hearing testimony, and the Presiding Officer's Report, the Commission also cited a survey by the American Association of Retired Persons, which found significant non-compliance and continued lack of consumer awareness of their rights, particularly among older consumers. *Id.* at 10303 & nn.180 & 181; *see also* Eyeglass II Report, *supra* note 14, at 263 n.682 (noting that 32% of consumers who did not receive a prescription stated that they did not know to ask for one).

[21] *See Cal. State Bd. of Optometry* v. *FTC,* 910 F.2d 976 (D.C. Cir. 1990). The court overturned provisions related to certain State laws of optometry, which the court found could not be overridden by the FTC without more explicit authority from Congress. Following the court decision, in 1992, the Commission reissued the Eyeglass Rule, but without the portions declared invalid, and with renumbered designations pertaining to prescription release. *See* Final Trade Regulation Rule, Ophthalmic Practice Rules, 57 FR 18822 (May 1, 1992).

[22] Ophthalmic Practice Rules, Request for Comments, 62 FR 15865, 15867 (Apr. 3, 1997).

[23] 15 U.S.C. 7601–7610 (Pub. L. 108–164).

[24] Pursuant to the FCLCA, the Commission promulgated the Contact Lens Rule (''CLR'') on July 2, 2004. Contact Lens Rule, Final Rule, 69 FR 40482 (July 2, 2004) (codified at 16 CFR part 315).

[25] Ophthalmic Practice Rules, Final Rule, 69 FR 5451, 5453 (Feb. 4, 2004) (''2004 ER''). The Commission also made findings that: release of prescriptions enhances consumer choice; no evidence had been submitted that the Rule's restrictions on disclaimers and waivers were no longer needed; the automatic-release provision imposed only a minimal burden on prescribers; and retaining automatic release would keep the Eyeglass Rule consistent with the automatic-release provision of the Contact Lens Rule, 16 CFR part 315.

[26] 2004 ER, 69 FR 5453.

[27] *Id.; see also* Contact Lens Rule, Final Rule, 69 FR 40482.

[28] 15 U.S.C. 57a(a)(1)(B).

[29] 15 U.S.C. 57a(d)(2)(B) (''A substantive amendment to, or repeal of, a rule promulgated under subsection (a)(1)(B) shall be prescribed, and subject to judicial review, in the same manner as a rule prescribed under such subsection.'').

[30] 15 U.S.C. 45(n); *see also* Eyeglass II Rule, 54 FR 10285, 10287; Letter from the FTC to Hon. Wendell Ford and Hon. John Danforth, Committee on Commerce, Science and Transportation, U.S. Senate, Commission Statement of Policy on the Scope of Consumer Unfairness Jurisdiction (Dec. 17, 1980), *appended to Int'l Harvester Co.,* 104 F.T.C. 949, 1070, 1073 (1984) (also referred to as ''FTC Policy Statement on Unfairness'': *https://www.ftc.gov/legal-library/browse/ftc-policy-statement-unfairness*).

[31] 15 U.S.C. 57a(b)(3).

[32] 15 U.S.C. 57a(b)(3)(B).

[33] Ophthalmic Practice Rules, Final Trade Regulation Rule, Statement of Basis and Purpose, 54 FR 10285, 10288 (1989) (citing Credit Practices Rule, Statement of Basis and Purpose, 49 FR 7740, 7742 (1980)).

[34] *See* Ophthalmic Practice Rules, Final Trade Regulation Rule, Statement of Basis and Purpose, 54 FR 10288.

[35] *Id.*

[36] *Id.*

[37] *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)).

[38] Contact Lens Rule, Request for Comment, 80 FR 53272 (Sept. 3, 2015) [hereinafter CLR RFC].

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

[40] ANPR, 80 FR 53276.

[41] The public comments responding to the ANPR are posted on *Regulations.gov* at *https://www.regulations.gov/document/FTC-2015-0095-0001* (ANPR Comments). *Regulations.gov* has assigned each comment an identification number appearing after the name of the commenter. This final rule cites comments using the last name of the individual submitter, or the name of the organization and the individual within the organization who submitted the comment, along with the last four digits of the comment identification number assigned by *Regulations.gov*. For instance, the full comment number assigned by *Regulations.gov* to the comment submitted by an individual named Publi is FTC–2015–0095–0040. In this document, that comment is cited as ''Publi (ANPR Comment #0040).'' This SBP will use this same identification method when discussing comments submitted in response to other rulemaking notices.

[42] *See, e.g.,* Opticians Association of Virginia (ANPR Comment #0647 submitted by Nelms) (stating that patients are led into the dispensary 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); Burchell (ANPR Comment #0866); National Association of Optometrists and Opticians (''NAOO'') (ANPR Comment #0748 submitted by Cutler); Professional Opticians of Florida (ANPR Comment #0803 submitted by Couch). Other commenters more generally stated their support for the Rule. *See* Publi (ANPR Comment #0040); Santini (ANPR Comment #0047); Costa (ANPR Comment #0068); Ellis (ANPR Comment #0189); Hildebrand (ANPR Comment #0220); Prevent Blindness (ANPR Comment #0385 submitted by Parry); DiBlasio (ANPR Comment #0441); Pulido (ANPR Comment #0019); Stuart (ANPR Comment #0841).

[43] AOA (ANPR Comment #0849 submitted by Peele); *see also* Barnes (ANPR Comment #0043) (stating she complies with the Rule although it is unnecessary since any ethical doctor will release a non-expired prescription to a patient); Kanevsky (ANPR Comment #0364) (optometrist states she and the prescribers she knows comply with the Rule).

[44] Contact Lens Rule, Notice of Proposed Rulemaking, 81 FR 88526 (Dec. 7, 2016) [hereinafter CLR NPRM].

[45] Contact Lens Rule, Supplemental Notice of Proposed Rulemaking, 84 FR 24664 (May 28, 2019) [hereinafter CLR SNPRM].

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

[47] *Id.* at 50687.

[48] *Id.*

[49] 16 CFR 315.3(c).

[50] CLR Final Rule, 85 FR 50687.

[51] *Id.* at 50687–88.

[52] CLR SNPRM, 84 FR 24668–69; CLR Final Rule, 85 FR 50681–83.

[53] CLR Final Rule, 85 FR 50717; 16 CFR 315.2.

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

[55] The public comments submitted in response to the NPRM are available on *Regulations.gov* at *https://www.regulations.gov/document/FTC-2023-0001-0001* (''NPRM Comments''). There are 47 comments available at this link. Twenty-seven comments were received in response to the Commission's NPRM, and 20 comments were submitted in response to a subsequent public notice. *See infra* note 59.

[56] Public Workshop Examining Proposed Changes to the Ophthalmic Practice Rules (Eyeglass Rule), Public Workshop and Request for Public Comment, 88 FR 18266 (Mar. 28, 2023) [hereinafter WS Notice].

[57] *Id.* at 18268.

[58] The workshop transcript (along with the agenda and a video recording) is available on the FTC website at *https://www.ftc.gov/news-events/events/2023/05/clear-look-eyeglass-rule* [hereinafter WS Transcript].

[59] The public comments submitted in response to the WS Notice are available on *Regulations.gov* at *https://www.regulations.gov/document/FTC-2023-0001-0029* [hereinafter WS Comments]. There are 47 comments available at this link. Twenty-seven comments were received in response to the Commission's NPRM, and 20 comments were submitted in response to the WS Notice.

[60] 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 Notice]; and the CLR SNPRM. Public comments received in response to these notices are available on *Regulations.gov: https://www.regulations.gov/document/FTC-2015-0093-0001* (CLR RFC Comments); *https://www.regulations.gov/document/FTC-2016-0098-0001* (CLR NPRM Comments); *https://www.regulations.gov/document/FTC-2017-0099-0001* (CLR WS Comments); and *https://www.regulations.gov/document/FTC-2019-0041-0001* (CLR SNPRM Comments). *Regulations.gov* has assigned each comment an identification number appearing after the name of the commenter. This document cites comments using the last name of the individual submitter, or the name of the organization and the individual within the organization who submitted the comment, along with the last four digits of the comment identification number assigned by *Regulations.gov*.

[61] The Commission has determined not to disturb that finding, even after analyzing comments suggesting it should do so. *See* section II.A, *infra.*

[62] *See* section II.A.1.a, *infra* note 126 and text, noting that two third-party surveys of eyeglass wearers reveal that the number of consumers not receiving their eyeglass prescription automatically after a refractive exam ranges from 25.6 million to 55.3 million a year (based on the Commission's estimate that 82.5 million consumers visit their eye care prescriber for a refractive exam each year). These figures are generally consistent with multiple prior surveys of contact lens users, which found significant percentages of contact lens users were not receiving their prescriptions from their prescribers following their exams, and provided an impetus for the adoption of a confirmation-of-prescription-release requirement in the CLR amendments of 2020. *See* section II.A.1.a, *infra* note 124; *see also* CLR Final Rule, 85 FR 50687.

[63] *See* 16 CFR 315.3.

[64] This final rule does not revisit some amendments that the Commission previously determined not to propose; namely, amending the Rule to require prescribers provide additional copies of eyeglass prescriptions; to require that prescribers respond to third-party seller requests for copies of, or verification of, prescriptions; or to set an expiration date for eyeglass prescriptions. In the NPRM, the Commission determined it did not need to seek further comment on these issues, and explained its rationale for not proposing these amendments. *See* NPRM, 88 FR 266–67 (additional copy), 271–73 (third-party seller requests), and 277–79 (expiration date).

[65] American Academy of Ophthalmology (''AAO''), ''Eye Health Statistics,'' *https://www.aao.org/newsroom/eye-health-statistics.* Estimates as to the number of

ophthalmologists vary, with some putting the number at closer to 17,000. Richard Edlow, ''By the Numbers: How Many ODs Are Actually Practicing Medical Eyecare,'' Rev. of Optm. Bus. (Nov. 3, 2021), *https://reviewob.com/by-the-numbers-how-many-ods-are-actually-practicing-medical-eyecare/.*

[66] In some States, optometrists can prescribe medicine and perform certain surgeries. AOA, ''What's a doctor of optometry?'' *https://www.aoa.org/healthy-eyes/whats-a-doctor-of-optometry*?

[67] Bureau of Labor Statistics, U.S. Dep't of Labor, Occupational Outlook Handbook, Optometrists, *https://www.bls.gov/ooh/healthcare/optometrists.htm.* Estimates as to the number of optometrists vary, with some putting the number at closer to 48,000. Edlow, *supra* note 65.

[68] Management & Bus. Acad. for Eye Care Prof'ls, ''Best Practices of Spectacle Lens Mgmt'' 2 (2015) (estimating revenue from prescription eyewear sales at 44% of total practice revenue, with contact lens sales revenue at 16%, eye exam revenue at 21%, and medical eye care revenue at 17%), *https://files.optometrybusiness.com/Best%20Practices%20Spectacle%20Lenses.pdf, see also infra* note 174, Lovejoy (WS Transcript at 19) (noting that data he has seen over the years shows that between 50–60% of gross revenues for practitioners who dispense eyewear is derived from product sales).

[69] *Id., see also* Margery Weinstein, ''Key Practice Metrics: Numbers to Track & Grow to Help Speed Practice Recovery,'' Rev. of Optm. Bus. (Aug. 5, 2020), *https://www.reviewob.com/key-practice-metrics-numbers-to-track-grow-to-speed-practice-recovery/* (noting that product sales in 2019 continued to account for the majority of gross revenue (54%), with eyewear at 37%) (citing Glimpse & Care Credit, ''Independent Optometry Key Performance Metrics: 2019 Trend Report'' at 5, 9)).

[70] OpticianEDU.org, ''Optician Certification,'' *https://www.opticianedu.org/optician-certification/.* The Commission has not independently verified the precise number of States that currently require opticians to obtain licenses.

[71] Bureau of Labor Statistics, U.S. Dep't of Labor, Occupational Outlook Handbook, Opticians, *https://www.bls.gov/ooh/healthcare/opticians-dispensing.htm.*

[72] Vision Council, ''VisionWatch—The Vision Council Market Analysis Report,'' at 17 (Dec. 2019) [hereinafter VisionWatch Report].

[73] Determining the precise number of adults, and adult eyeglass wearers, in the United States at any given time, is not possible, and estimates will change every year. According to the U.S. Census Bureau, in 2020 there were 258.3 million adults in the United States. ''U.S. Census Bureau, Age and Sex Composition: 2020,'' 2020 Census Briefs (2023), *https://www2.census.gov/library/publications/decennial/2020/census-briefs/c2020br-06.pdf.* Meanwhile, four different surveys of U.S. residents in 2021 and 2022 by The Vision Council found that 61–65% of adults wear glasses, which equates to approximately 158–168 million adults who wear eyeglasses, based on the 2020 census. Vision Council Consumer inSights reports 2022 Q1, Q2, Q3, Q4. In its NPRM, the Commission used a prior Vision Council estimate of 165 million adult eyeglass wearers, NPRM, 88 FR 252, which is within the 158–168 million range.

[74] The Vision Council, Market inSights 2022.

[75] The Vision Council, Market inSights 2019–2022.

[76] Vision Council Consumer inSights Report Q1 2023 at 23, 42.

[77] *See* Opticians Association of America (NPRM Comment #20) (noting that according to Optics Magazine, the online eyewear industry will continue to experience a compound annual growth rate of 6.96% between 2022 and 2027).

[78] Vision Council Consumer inSights Report Q2 2023 at 39, 42.

[79] Vision Council Consumer inSights Report Q2 2023 at 41.

[80] *See, e.g.,* Practice Tips by First Insight Corporation, ''How to Calculate and Increase Your Optical Capture Rate,'' (July 6, 2021), *https://www.first-insight.com/blog/calculate-increase-optical-capture-rate/*; Eric Rettig, ''How We Increased Frame Capture Rate by 20% in 3 Years,'' Rev. of Optm. Bus. (Sept. 7, 2022), *https://reviewob.com/how-we-increased-frame-capture-rate-20-in-3-years/.*

[81] Vision Council Market inSights 2022 at 11.

[82] Catherine Roberts, ''Get Great Glasses For Way Less,'' Consumer Reports, Oct. 2023, at 36.

[83] *Id.*

[84] *Id.*

[85] 16 CFR 456.2(a).

[86] 16 CFR 456.2; *see also* Presiding Officer's Report, *supra* note 19, at 17–24, 206.

[87] Eyeglass I Rule, 43 FR 23992; Eyeglass II, 54 FR 10302; *see also* Eyeglass I Report, 261, 265. (''[W]ith prescription in hand, consumers would be free to seek out the price, quality and other features which best suit their needs and capabilities.'' The ophthalmic prescription is ''the means by which consumers can comparison shop,'' and thus ''[i]f the Commission does not act to guarantee consumers their prescriptions, consumers may be unable to take full advantage of this competition.'').

[88] *See* 2004 ER, 69 FR 5453.

[89] Neilly (WS Transcript at 4–5).

[90] *Id.* at 5.

[91] *Id.*

[92] Formerly known as the National Association of Optometrists and Opticians, or NAOO.

[93] NAROC (NPRM Comment #0024 submitted by Neville).

[94] Durkee (NPRM Comment #0015).

[95] Michaels (WS Transcript at 14).

[96] *Id.* at 7; *see also* Cooper (NPMR Comment #0009) (asserting that patients are receiving their prescriptions, the problem lies with inaccurate filling of these prescriptions by ''unlicensed, untrained people'').

[97] AAO (NPRM Comment #0027 submitted by Repka).

[98] OAA (NPRM Comment #0020 submitted by Allen); AOA (WS Comment #0047 submitted by Benner).

[99] AOA (NPRM Comment #0023 submitted by Benner).

[100] Michaels (WS Transcript at 11).

[101] Sanders (WS Comment #0043) (Dr. Sanders' calculation is based on comparing his assumptions about the number of complaints received by the FTC to his estimate that prescribers perform 236 million refractions every year, an estimate the FTC has not seen evidence supporting); *see also* Coast Eyes Pllc (WS Comment #0046) (''Nothing is broken here. Patients get their prescription without conflict. . . . Prescribers are historically >99.9% compliant in the market's current state.'') Coast Eyes Pllc is operated by Dr. Sanders.

[102] AOA (WS Comment #0047 submitted by Benner).

[103] While the ophthalmic community has repeatedly stated that overall prescriber compliance with prescription release is extremely high, the community has not offered the FTC a consumer survey on this issue, despite repeated comments from the Commission noting the absence of empirical evidence to support their claim of substantial compliance, or to rebut the multiple consumer surveys in the record which show prescriber non-compliance. *See* NPRM, 88 FR 260 (''the Commission notes, as it did in the CLR Final Rule, that despite multiple opportunities and requests for comment since 2015, the Commission has yet to find or receive any reliable consumer-survey data rebutting or contradicting the submitted findings [showing compliance problems] for either contact lens users or eyeglass wearers, or establishing (other than anecdotally) that consumers consistently receive their prescriptions from prescribers.''). Indeed, when suggesting that the Commission consider the NERA survey, the AOA referenced the repeated comments from the Commission about the lack of survey data evidencing compliance. AOA (WS Comment #0047 submitted by Benner).

[104] AOA (WS Comment #0047 submitted by Benner).

[105] *Id.* According to Dr. Andrew Stivers from NERA Consulting, the survey did not specifically ask about compliance with the Rule's automatic-prescription-release requirement because the survey was not designed to examine compliance, but rather to examine consumer conduct and shopping habits for eyewear and, consequently, explore the ongoing *need* for consumers to possess a copy of their prescription. According to Dr. Stivers, whether prescribers are automatically providing patients with their prescriptions is not as relevant if the manner in which consumers purchase eyewear indicates that they don't suffer harm (or as great a harm) from not having their prescriptions released automatically. ''I do not address the Commission's contention of significant non-compliance with automatic release, although the provided evidence suggests a relatively limited problem, and does not provide evidence linking such a problem to harm today.'' Stivers (NPRM Comment #0018).

[106] AOA (WS Comment #0047 submitted by Benner).

[107] It is also not certain that there were not more than three respondents who mentioned a prescriber's failure to release their prescription. According to NERA, due to budgetary constraints, responses to open-

ended questions were not formally coded and reviewed. Rather, NERA searched all open-ended responses for variations of the words ''prescription,'' ''Rx,'' ''had to,'' ''forced,'' ''made to,'' ''choice,'' and ''pressure.'' AOA (WS Comment #0047 submitted by Benner). The three consumers who raised the issue of failure to release the prescription were identified via this search. It is possible, however, that additional respondents may have referenced a prescriber's failure to release prescriptions but used words or phrases that did not show up during NERA's targeted search, and the Commission did not receive the responses to the open-ended questions. This adds to the challenge of ascribing weight to, or drawing conclusions from, responses (or the lack of responses) to open-ended survey questions.

[108] *See* CLR Final Rule, 85 FR 50676; CLR SNPRM, 84 FR 24674–75. By some estimates, less than 5% of actual fraud victims file complaints, and for consumer complaints about FTC rule violations the percentage drops even further, perhaps because filing a complaint requires that consumers know what an FTC rule specifies, that it has been violated, and how to complain to the FTC about it. *Id.* It has generally been the Commission's experience that while a large number of complaints can indicate a rule compliance problem, a dearth of complaints does not necessarily indicate that there isn't a rule compliance problem.

[109] Neilly (WS Transcript at 16).

[110] Warby Parker (ANPR Comment #0817 submitted by Kumar). The October 2015 SurveyMonkey online survey was comprised of 1,329 respondents recruited from a sample that was U.S. Census-balanced and representative of the national distribution of major demographic factors, including age, gender, geography, and income. Respondents 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 respondents 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 between one and three years prior to the survey. The significant difference in automatic-release compliance between optometrists and ophthalmologists may be due to the fact that fewer ophthalmologists sell eyeglasses, and might thus have less incentive to withhold a consumer's prescription, but the survey did not directly explore this issue. *See* ER NPRM, 88 FR 260 note 174.

[111] *Id.*

[112] ''FCLCA Study, Focus on Prescription (Rx)'' at 2, 9, attached as Exhibit B to 1–800 CONTACTS's comment in response to the FTC's 2015 Request For Comment (CLR RFC Comment #0555 submitted by Williams), *https://www.regulations.gov/comment/FTC-2015-0093-0555,* showing that of 303 eyeglass wearers surveyed, only 61% reported receiving a ''hard copy'' of their prescription at their last eye exam. Of that 61% who received a copy of the prescription, the poll found that 55% were given the copy automatically (in other words, approximately 34%—55% of 61%—of the total eyeglass wearers surveyed were given a copy in full compliance with the Rule), 31% of the 61% were not given a copy automatically but requested their prescription and were given it immediately in response (19% of the total surveyed), and 14% of the 61% were not given a copy of their prescription, asked for it, and were told to call the office or return for it at a later time (8.5% of the total surveyed). 39% of the total eyeglass users surveyed were not given a copy and did not ask for it, and thus never received a copy of their prescription. The survey was sponsored by 1–800 CONTACTS but conducted by an independent third-party polling firm, SSI, and respondents were not informed of the identity of the survey sponsor. As explained *infra* note 124, the Commission has recognized some concerns about the methodology used for this survey, particularly the use of the word ''hard copy,'' and the lack of an ''I don't know'' response option for some questions, but believes that the information remains strongly suggestive of non-compliance, particularly when viewed in conjunction with information from other sources and the absence of contradictory data.

[113] *Id.*

[114] *See* Coast Eyes Pllc (WS Comment #0046) (''The 'data/surveys' provided to the FTC that they are guiding their decision on come from online retailers who have a HUGE conflict of interest.'').

[115] AOA (WS Comment #0047 submitted by Benner) (''We [ ] question the FTC deriving much of its eyeglass rulemaking from its rulemaking on contact lenses. The eyeglass market and contact lens market have unique characteristics.'').

[116] *Id.* (quoting NERA Report). It was also noted that the median age of eyeglass patients is likely to be higher than that for contact lenses, and older patients are more likely to be confused or bothered by the need to sign a confirmation document. Repka (WS Transcript at 38–39).

[117] AOA (WS Comment #0047 submitted by Benner) at 25 (''[G]lasses purchasers are 10 percentage points more likely to consider other options for where to purchase.'').

[118] *Id.* A primary difference between eyeglass and contact lens examinations and prescriptions is that contact lens exams involve a lens ''fitting,'' in which consumers try on the lenses, and prescriptions are only provided after the fitting is complete. Fittings can sometimes entail sending consumers home with a set of lenses to try out for a few days, and thus sometimes the prescriber will not provide the prescription until after this process. This can lead some consumers to think they should have been provided their prescriptions when, in fact, the fitting was not yet complete. There is no such fitting for eyeglass prescriptions. *See also infra* note 123 (discussing how the different processes can affect survey results about prescription release).

[119] *See* CLR Final Rule, 85 FR 50675; CLR SNPRM, 84 FR 24673.

[120] Warby Parker (ANPR Comment #0817 submitted by Kumar).

[121] ''FCLCA Study, Focus on Prescription (Rx)'' at 2, 9, *supra* note 112.

[122] In particular, these survey results could not have been affected by some consumers erroneously thinking they should have received their prescriptions when, in fact, their contact lens fitting had not been finalized, since eyeglass prescriptions do not entail a fitting, and there is little or no reason for a consumer to think their eyeglass prescription had been finalized when, in fact, it hadn't been.

[123] *See supra,* note 118, explaining the fitting process for contact lenses. In theory, the differences between the contact lens prescription process and the eyeglass prescription process should mean that fewer eyeglass patients are confused as to whether they did or did not receive their prescriptions when they were supposed to. The fact that the percentage of eyeglass users surveyed who said they did not receive their prescriptions is similar, or even higher than that of contact lens wearers surveyed adds considerable credence to both types of surveys, and provides further support for the conclusion that a substantial number of consumers are not automatically receiving their prescriptions from prescribers as the Eyeglass Rule requires.

[124] The results from the individual consumer contact lens surveys are as follows: (1) June 2019 survey by Dynata (formerly known as SSI) 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 #0135 submitted by Montclair)); (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 #2954 submitted by Sherry)); (3) December 2016 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 #2738 submitted by Williams)); (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 RFC Comment #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 #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 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 understand. The more recent 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 24672.

[125] *See* CLR Final Rule, 85 FR 50675.

[126] *See* section I.D.4, *supra* note 62. Since it is estimated that 165 million Americans regularly wear prescription glasses, and that each patient visits their eye care prescriber every two years for a refractive exam, the number of consumers not receiving their prescription automatically could be as high as 55.3 million a year, based on the Survey Sampling International survey, or 25.6 million, based on the SurveyMonkey poll. Multiple surveys in the record of contact lens users find similar non-compliance with prescription release requirements.

[127] Eyeglass I Rule, 43 FR 24003 (''[I]t is the Commission's finding that the failure to release ophthalmic prescriptions and related practices are unfair acts or practices,'' and such practices ''offend public policy in that they deny consumers the ability to effectively use available information and inhibit the functioning of the competitive market model.'').

[128] NAROC (NPRM Comment #0024 submitted by Neville).

[129] NAROC (WS Comment #0049 submitted by Neville).

[130] Lovejoy (WS Transcript at 14).

[131] 1–800 CONTACTS (NPRM Comment #0025 submitted by Montclair); *see also* Durkee (NPRM Comment #15) (calling it a ''borderline unethical practice'' not to automatically release prescriptions, and favoring more robust enforcement of the existing automatic-release requirement rather than adding a confirmation requirement.)

[132] Anonymous (WS Comment #0030).

[133] Brown (WS Transcript at 13).

[134] *Id.*

[135] Aceto (WS Transcript at 45–46).

[136] Beatty (WS Transcript at 46).

[137] Dr. Stivers, a former Deputy Director for Consumer Protection in the FTC's Bureau of Economics, now an economics consultant with NERA, submitted a comment (NPRM Comment #0018) in response to the NPRM. That comment, and his research into consumer experience with eyeglass purchases, was sponsored by the American Optometric Association. His appearance as a workshop panelist, however, was on his own behalf.

[138] Stivers (WS Transcript at 17).

[139] *Id.* at 18–19; *see also* Beatty (WS Transcript at 46) (noting that many patients are given a copy but do not still have it later on when they need it. And therefore he recommends merely ensuring that patients can request a copy of their prescription and access it electronically).

[140] Stivers (WS Transcript at 10, 17); Stivers (NPRM Comment #0018).

[141] Stivers (NPRM Comment #0018).

[142] *Id.*

[143] *Id.*

[144] *Id; see also* Stivers (WS Transcript at 12) (''[T]he big thing that has really changed is the ability of consumers to find prices, to shop to find competitors, before they even leave their house. Before the internet, before good information availability, really the only way to price compare, if there was also these advertising restrictions was to actually go to the establishment.''); Montaquila (WS Transcript at 32) (stating that people often come to his office knowing beforehand where they plan to purchase eyewear); Michaels (WS Transcript at 14) (agreeing that most patients today are evaluating their options before they wind up in a brick-and-mortar establishment). *But see* Michaels (WS Transcript at 13) (noting that many patients come in for an eye health examination even if they do not think they need glasses, and thus would not have decided beforehand where to purchase).

[145] Stivers (NPRM Comment #0018).

[146] *Id.*

[147] AOA (WS Comment #0047 submitted by Benner) (quoting NERA report).

[148] *Id.*

[149] *Id.*

[150] *Id.* (''Consumer emphasis on convenience suggests that consumers likely consider both where to get an exam and where they want to shop for glasses ahead of time for an efficient shopping experience.'') (quoting NERA survey).

[151] Stivers (WS Transcript at 20).

[152] Some prescribers are known to engage in a practice referred to as ''prescribing from the chair,'' in which prescribers recommend certain eyewear purchases to patients while the patients are still in the exam room. This is touted as a means of increasing prescribers' eyewear-sale capture rate. *See, e.g.,* Dr. Gayle Karanges, ''The 4 Most Powerful Ways I Prescribe from the Chair and Contribute to an 82% Eyewear Capture Rate,'' Rev.of Optm. Bus. (Apr. 7, 2021) (''Patients often view doctors, including optometrists, as authority figures. With that status, you have an opportunity to influence patients in their decision to follow your treatment plan and purchase the eyewear you have prescribed.''), *https://reviewob.com/the-4-most-powerful-ways-i-prescribe-from-the-chair-contribute-to-an-82-eyewear-capture-rate/*; Practice Tips by First Insight Corporation, ''How to Calculate and Increase Your Optical Capture Rate,'' Jul. 6, 2021 (describing how one doctor ''recommends and prescribes the eyewear needs while the patient is still in the exam chair . . . [and] then invites and guides the patient to the optical department, introducing the eyewear layout''), *https://www.first-insight.com/blog/calculate-increase-optical-capture-rate/.* The FTC is unaware how widespread this practice is, but it has concerns that such practices can further blur the line between medical practice and retail sales, and increase the risk that patients may feel undue pressure to purchase eyewear from their prescriber.

[153] Michaels (WS Transcript at 13).

[154] As an example, surveys from The Vision Council have found that 83% of consumers who recently had an eye exam and bought glasses said they purchased the glasses from their prescriber. The Vision Council, Consumer inSights Q1 2022. One interpretation of this might be that only 17% of consumers benefit from having a copy of their prescription with which to shop elsewhere. This seems supported by the NERA survey showing convenience is the most important factor in a consumer's decision as to where to buy glasses. On the other hand, another interpretation is that 83% of consumers buy glasses from their prescriber because many were not given their prescription, and they either felt uncomfortable demanding it or did not know that they could. This interpretation could also be supported by the NERA survey, since the survey found that price is the second-most important factor for consumers deciding where to purchase glasses, and buying glasses from a prescriber is often more expensive than other options. Because so many consumers do not currently receive their prescription after each exam, looking to their current conduct and behavior to determine what would happen if they did receive their prescription involves a great degree of speculation.

[155] *See, e.g.,* Lovejoy (WS Transcript at 15); National Taxpayers Union (NPRM Comment #0028 submitted by Sepp) (stating that the Eyeglass Rule has been a huge ''boon'' to competition in the marketplace).

[156] Lovejoy (WS Transcript at 15).

[157] Eyeglass I Rule, 43 FR 24003 (declaring that Rule § 456.7 (now § 456.2), which provides it is an unfair act or practice for a refractionist to fail to release a prescription immediately after the eye examination is completed, is justified ''both as a specific delineation of an unfair act or practice as well as a remedy to implement the right to advertise.'').

[158] *See, e.g.,* Montaquila (WS Transcript at 32) (patients already understand what their choices are before they even come in for an exam); Michaels (WS Transcript at 14) (noting that most patients seem to be evaluating their purchase options before they visit their prescriber).

[159] *See, e.g.,* Neilly (WS Transcript at 16) (''Before I got this notification [about the Eyeglass Rule workshop], I wasn't even aware of an eyeglass rule.''); Anonymous (WS Comment #0030) (''Being able to have a prescription in your hands as soon as the examination is done would be very beneficial.'').

[160] Brown (WS Transcript at 17). Dr. Stivers noted in a comment that a Commission-sponsored survey in 1981 (the Market Facts Survey) found that a significant percentage of consumers, even then, were aware that they did not have to buy eyeglasses from their examining eye doctor and could ask for their prescription. Stivers (NPRM Comment #0018) at 9. This is not incorrect (the Market Facts Survey results indicated that ''a large majority of consumers are knowledgeable enough to request an eyeglass prescriptions if they want one,'' Eyeglass II Report, *supra* note 14, at 262), but it should be noted that another survey conducted around that time (in 1985, by the American Association of Retired People) found that 83% of consumers—particularly the elderly—remained unaware of their right to ask for their prescription. Presiding Officer's Report at 22. It may also be worth noting that the format and phrasing of the Market Facts Survey questions may have been flawed (and came under criticism) because consumers were simply asked whether it was true or false that ''once a person decides where to have his eye examined, he must purchase his eyeglasses from his doctor,'' creating the possibility that some consumers answered ''false'' not because they understood they were free to take their prescription and shop elsewhere, but rather because they knew they

could not be forced to buy eyeglasses if they didn't want to. Eyeglass II Report, *supra* note 14, at 259–61. The Commission, after reviewing both the Market Facts and AARP surveys, and other evidence in the record, ultimately concluded at that time that ''there continues to be a lack of consumer awareness about prescription rights.'' Eyeglass II, 54 FR 10303. The two surveys are now roughly 40 years old, and more recent surveys show that many consumers are not fully aware of their prescription rights. *See infra* notes 161–163 and text.

[161] As with the SSI survey referenced above, the 2015 survey performed on behalf of 1–800 CONTACTS was submitted during the Contact Lens Rule review, but it was a poll of eyeglass wearers and is therefore on point. 1–800 CONTACTS (CLR NPRM Comment #2738 submitted by Williams). As noted during the Contact Lens Review, 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 that should be accorded to the results. In particular, the questions were leading and used a term—''hard copy''—that some consumers might not understand. On the other hand, the question's phrasing may have led to under-reporting by consumers who did not want to acknowledge that they were unaware of their rights under Federal law (this is known as social-desirability bias). *See* Diamond, *Reference Guide on Survey Research,* in Reference Manual on Scientific Evidence, 2nd. ed., 248–64 (Federal Judicial Center 2000), *https://wwws.law.northwestern.edu/faculty/fulltime/diamond/papers/referenceguidesurveyresearch.pdf;* Floyd Jackson Fowler, Jr., *How Unclear Terms Affect Survey Data,* The Public Opinion Quarterly (Summer 1992), *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 133–36 (2017), *https://www.sciencedirect.com/science/article/abs/pii/S0306460317301752?via%3Dihub* (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 attitudes and behaviors that may be considered desirable attributes, while underreporting less desirable attributes). Social-desirability bias in this instance likely serves to artificially lower 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 #0555 submitted by Williams) (One question was phrased, ''Are you aware that it is your right under federal law, as a patient to receive a hard copy of your contact lens/eye glasses prescription from your eye exam provider?'' and the other asked, ''Are you aware of the following . . .—Your eye exam provider cannot charge you for an actual hard copy of your prescription?'').

[162] CLR SNPRM, 84 FR 24675 (citing a Caravan ORC International survey submitted by Consumer Action (CLR NPRM Comment #2954 submitted by Sherry) and SSI survey submitted by 1–800 CONTACTS (CLR NPRM Comment #2738 submitted by Williams)).

[163] *See* Consumer Action (CLR NPRM Comment #2954 submitted by Sherry) (noting survey results showing that 65% of Hispanics and 63% of African Americans were unaware of their prescription rights, compared to 58% of white Americans surveyed, and that Hispanics were less likely to be given copies of their prescriptions after their contact lens exams); National Hispanic Med. Ass'n & League of United Latin Am. Citizens (CLR SNPRM Comment #0146 submitted by Benavides) (''Our community continually has been victimized and denied their prescriptions by prescribers and doctors at a higher rate than most other Americans''); League of United Latin Am. Citizens (CLR NPRM Comment #2336 submitted by Wilkes) (noting that many ''working families'' take time off from work to visit their eye doctor because they believe their eye doctor is the only place to buy eyewear).

[164] CLR SNPRM, 84 FR 24675; *see also supra* note 152 and text, noting that some prescribers blur the separation between exams and retail dispensing as a means of improving their eyeglass sales ''capture rate.''

[165] CLR SNPRM, 84 FR 24675.

[166] *Id.*

[167] *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)).

[168] 16 CFR 456.2.

[169] *See* Aceto (WS Transcript at 52); Santini (ANPR Comment #0047) (prescribers should be required to provide a copy of the eyeglass prescription before the consumer is led or enters the prescriber's optical dispensary); Opticians Ass'n of VA (ANPR Comment #0647 submitted by Nelms) (''More often than should be occurring, patients are led into the dispensary before paying for the exam, and shown their options for eyewear. We would ask the Rule be amended to include language that the prescription must be given to the patient on completion of the exam without additional sales pressure or intimidation.'').

[170] *See* Practice Tips by First Insight Corporation, ''How to Calculate and Increase Your Optical Capture Rate'' (Jul. 6, 2021) (describing how one doctor ''recommends and prescribes the eyewear needs while the patient is still in the exam chair . . . [and] then invites and guides the patient to the optical department, introducing the eyewear layout''), *https://www.first-insight.com/blog/calculate-increase-optical-capture-rate/*; Nicole Lovato, ''3 Things We Did to Increase Capture Rate by 15%,'' Rev. of Optm. Bus. (Oct. 27, 2021) (describing how after each exam visit, the doctor or a technician will walk the patient to the optical dispensary to try and sell them glasses, and ''pulls out a chair from the table and tells the patient, 'Have a seat, someone will be right over to get you finished up.' It is important to state it this way. If you say anything about purchasing it gives the patient an opportunity to say they are not interested.''), *https://reviewob.com/3-things-we-did-to-increase-capture-rate-by-15/. See also supra* notes 80, 152.

[171] Botha (WS Transcript at 53).

[172] 16 CFR 456.2(a).

[173] Eyeglass I Rule, 43 FR 23992. *See* section I.B, *supra* (discussing the history and purpose of the Rule).

[174] In most medical fields, a prescriber is prohibited from selling the product that they prescribe so as to prevent potential conflicts of interest. *See generally* Limitation on Certain Physician Referrals (commonly known as the ''Stark Law'') 42 U.S.C. 1395nn, (prohibiting physician self-referral, including for outpatient prescription medications); Anti-Kickback Statute, 42 U.S.C. 1320a–7b(b) (prohibiting physicians from receiving compensation for a prescription referral). While there are a few other medical professions apart from eyecare—such as veterinary care—in which the prescriber may sell what they prescribe, the Commission is unaware of another field in which prescribers generate such a substantial share of their income from commercial product sales. *See* Lovejoy (WS Transcript at 19) (''I do think that optometry is unique among the healthcare professions in the amount of revenue, the percentage of the total revenue that comes from product sales, the products that they prescribe. The surveys that I've seen and information over the years shows it consistently staying over 50%, maybe as high as 55 or 60% of gross revenues comes from product sales in the practitioners that are dispensing optometrists.''); NAROC (WS Comment #0049 submitted by Neville) (''Private dispensing optometrists today still make most of their revenue from selling the eyewear that they prescribe. These optometrists have a strong incentive to improve the 'capture rate' of in-office eyewear sales to their patients.'').

[175] H.R. Rep. No. 108–318 at 5 (2003); *see also* Letter from Senators Richard Blumenthal and Orrin G. Hatch of the U.S. Senate Regarding the Contact Lens Rule Rulemaking Proceeding & the Proposed Rule Set Forth in the Notice of Proposed Rulemaking (Aug. 11, 2017), *https://www.ftc.gov/system/files/filings/initiatives/677/public_comment_from_senators_blumenthal_and_hatch_re_contact_lens_rulemaking.pdf* (these comments were made in reference to the contact lens marketplace, but the same potential conflict of interest exists when eyeglass prescribers also sell eyeglasses to their patients).

[176] Eyeglass I Report, *supra* note 7, at 265.

[177] The ophthalmic community and its representative associations were once fervent advocates for the ''total vision care'' approach to eyecare, and argued that patients received the best care when they obtained glasses and contacts from the same eye doctor who examined them and determined their prescription. *See* Eyeglass I Report at 236–39. While the AOA no longer publicly advocates for ''total vision care,'' some prescribers still occasionally comment to the FTC that patients would be best served by a total-vision-care approach.

[178] *See* section I.D.5, *supra,* discussing the benefits of in-person eyeglass fittings.

[179] This is a different situation from patients complaining that they did not

receive their prescription from their prescriber even after paying for their exam, or had to ask for their prescription in order to get a copy. There is much less room for consumer confusion with respect to those types of complaints than for complaints that consumers had to pay for their prescription.

[180] The majority of patients who go in for an eye exam and need new glasses do end up purchasing them from their prescriber. According to data from The Vision Council, 83% of consumers surveyed who recently had an eye exam and bought glasses said they purchased the eyewear from their prescriber. The Vision Council, Consumer inSights Q1 2022. This is true even though, on average, prescribers charge significantly higher prices for eyeglasses than other alternatives such as online eyeglass sellers. The Vision Council, Market inSights 2019–2022.

[181] 16 CFR 456.2(a).

[182] There are situations where a doctor may conduct a refractive exam on a patient but then use his or her professional judgment to refrain from writing a prescription for corrective eyewear. *See* Lovejoy (WS Transcript at 56) (''[C]onsumers may want a prescription when they shouldn't have one [for medical reasons], and the potential prescriber, the physician or optometrist, ought to have the ability to say, 'No, I'm not prescribing eyewear for you for the following reasons.' And make a note of that in the record.''). In such situations, the prescriber would have no reason to offer to sell the patient eyewear and would be prohibited from doing so under the Rule.

[183] Panelists at the workshop discussed whether greater clarity in the Rule could help ensure that patients have their prescription in hand before being invited to purchase eyeglasses. *See* Aceto (WS Transcript at 52) (''That's one concern that some of our optician members have had some concerns with, and that is at the end of the actual doctor's exam, oftentimes they're directed to the dispensary just as a matter of course, and they purchase [eyeglasses] at the end of the actual [exam]. And the copays, the exam fees, the glasses are all taken [together]. Then they said, here's your eyeglass prescription. And some of our members have asked, is there a way that we could clarify that the prescription should come to them at the end of the doctor's experience?'').

[184] The Commission realizes that some eye care practices advertise a bundle where the consumer pays a fixed price for an eye examination and one or more pairs of frames, or complete eyeglasses. Such an offer may also be advertised as an opportunity to obtain a free eye exam with the purchase of eyeglasses. The amendment to the Rule's wording is not intended to change those practices' ability to make, and lawfully deliver upon, such offers. However, the prescriber must still provide the prescription to the patient before offering to sell them eyeglasses. By doing so, the patient should have the choice to take advantage of the advertised bundle, or to pay the practice's routine cost of an examination and walk away with no eyeglasses, but with their prescription. The exam cannot be contingent on the purchase of eyeglasses, as stated in the Rule. *See* 16 CFR 456.2. The Commission has provided guidance with respect to the Contact Lens Rule for similar bundles of eye exams offered with contact lenses, instead of eyeglasses. In that context, the Commission has stated that a prescriber is not prohibited from offering a bundled package of an eye examination and contact lenses, provided that consumers have an option to purchase the eye examination separately and still receive their prescription. Contact Lens Rule, Final Rule, 69 FR 40482, 40494. A similar result is appropriate here.

[185] CLR SNPRM, 84 FR 24675; Eyeglass I Rule, 43 FR 23998.

[186] NPRM, 88 FR 268–69.

[187] NPRM, 88 FR 268.

[188] *Id.*

[189] *Id.*

[190] CLR Final Rule, 85 FR 50717; 16 CFR 315.2.

[191] CLR SNPRM, 84 FR 24668.

[192] OAA (NPRM Comment #0020 submitted by Allen) (''OAA believes that this revision ensures that the FTC's regulatory language is keeping pace with updates in technology.''); 1–800 CONTACTS (NPRM Comment #0025 submitted by Montclair) (''1–800 also supports . . . allowing prescribers to release a prescription in digital format with a patient's verifiable affirmative consent to a specific method for digital delivery.''); Aceto (WS Transcript at 42) (''[F]rom the optician standpoint and those who fill the prescription, it's sort of brilliant. Because again, we're keeping up with our current status of technology. It helps people, it's an all about an access type thing, and I think that that's a really, really good option.'').

[193] AOA (NPRM Comment #0023 submitted by Benner).

[194] NAROC (NPRM Comment #0024 submitted by Neville).

[195] Anonymous (NPRM Comment #0007) (''Most practices have an EMR system that also has a patient portal. Most of these patient portals provide access to the eye glass prescription. This new 'rule' is not necessary. If there is ever a question, the EMR system will always have a copy of the prescription available for anyone that wants it.''); Anonymous (NPRM Comment #0011) (''In 2009 The Hitech Act was passed which assured the use of electronic medical records. The EMR (The Electronic Medical Records Mandate) requires healthcare providers to convert all medical charts to a digital format. Incurring more costs on businesses for storage, paper, ink, private and government payroll, etc., is not an [ ] economically intelligent idea in a recession driven economy.''); Michaels (WS Transcript at 7) (''in my experience, 100% of the prescriptions that are coming out of our offices are automatically uploaded electronically to a portal the very second that the prescription is finalized. . . . That was the most important piece of the MIPS program that Medicare had. It mandated that patients get access to their portals. And so, in our experience, the vast majority of our patients don't want paper copies of the prescription. They want electronic copies so that they can have access in their phone and access at 2:00 in the morning, whenever they want it.'').

[196] Anonymous (NPRM Comment #0006). *See also* Rosemore (WS Comment #0045) (''As an optometrist, the added requirements would be a significant burden on my practice. Requiring more paperwork, consents, data storage, and time makes the cost of doing business go up significantly.'').

[197] One workshop participant suggested that prescribers who use electronic health records should not be required to transcribe an electronic prescription into a handwritten one, as this could introduce errors into the prescription. *See* Montaquila (WS Transcript at 22) (''Handwriting prescriptions after generating one in an electronic format increases time and cost, and is not risk-free. Researchers at Weill Cornell Medical College found error rates of 30 per 100 written prescriptions, and only seven per 100 electronic prescriptions. Now, that of course was from medications, but I would propose that contact lenses are no less complex when written on a sheet of paper.''). The FTC's requirement that patients be given the option to receive a paper copy would not necessitate a prescription to be converted from an electronic record to a handwritten one; instead the prescription could be printed out on paper, as was described by other workshop participants. *See* Hyder (WS Transcript at 53) (''If it's coming from the EHMR, I tend to get that when I'm checking out because it's being printed someplace other than the exam room.'').

[198] *See, e.g.,* U.S. Dep't of Health & Human Servs., The Office of the National Coordinator for Health Information Technology (''ONC''), ''Do I Need to Obtain Consent From My Patients to Implement a Patient Portal?,'' *https://www.healthit.gov/faq/do-i-need-obtain-consent-my-patients-implement-patient-portal* (noting that the Health Insurance Portability and Accountability Act (''HIPAA'') permits the disclosure of health information to the patient without requiring the patient's express consent and that portals are ''an excellent way to afford patients access to their own information and to encourage them to be active partners in their health care.'').

[199] CLR SNPRM, 84 FR 24668.

[200] U.S. Dep't of Health & Human Servs., ONC, ''Individuals' Access and Use of Patient Portals and Smartphone Health Apps, 2022,'' Data Brief: 69 (2023), *https://www.healthit.gov/sites/default/files/2023-10/DB69_IndividualsAccess-UsePatientPortals_508.pdf.*

[201] *Id.*

[202] National Institutes of Health, National Cancer Institute, Health Information National Trends Survey, Hints Brief Number 52, ''Disparities in Patient Portal Communication, Access, and Use'' (2020), *https://hints.cancer.gov/docs/Briefs/HINTS_Brief_52.pdf* (''[S]ignificant disparities exist in patient portal use, with underserved groups (including racial and ethnic minorities, those with lower socioeconomic status, older individuals, and persons with disabilities) using these tools less often.'').

[203] *Id.*

[204] U.S. Dep't of Health & Human Servs., ONC, ''Individuals' Access and Use of Patient Portals and Smartphone Health Apps, 2022,'' *supra* note 200.

[205] *See, e.g.,* Hyder (WS Transcript at 43) (''I would say that we're supportive of giving the option for digital prescriptions. But again, we would agree with not mandating that every type of digital option be available.''); Beatty (WS Transcript at 42) (''I think we do have to be careful with how we consider that delivery though. Requirements for that delivery to include all of the methods, including SMS and MMS, would or could actually produce new burden. Not everyone who delivers these things electronically has access to an SMS system or an MMS system. And so we'd want to be able to provide the possibility of delivering them electronically, but also allow for the provider to have the choice of how the electronic delivery would occur.'').

[206] NAROC (NPRM Comment #0024 submitted by Neville) (''We note with approval that the prescriber will not be required to offer a digital copy of the prescription, which some prescribers may not be able to offer. But we also suspect that those prescribers using digital release for contact lenses will likely use it for eyeglass prescriptions as well, again, adding efficiency to office operations.'').

[207] Lovejoy (WS Transcript at 45) (''Well, I do think it is easier . . . if a patient can get a prescription through email either directly of the prescription itself or to a link to a website or a portal where they can obtain it. And anecdotally I've heard reports of being able to be standing at the office desk checking out and having the prescription emailed to you before you leave the office. It's in your iPad or your iPhone and ready to be used wherever you might want to use it.''); Hyder (WS Transcript at 45) (''I would say that it gives providers more ability to comply, but I can't say that we have data to show that it improves compliance.'').

[208] NPRM Comment #0006 (''What happens when they access their portal and print the prescription off from there? Will our portals have to update to require a signature as well?'').

[209] Repka (WS Transcript at 26) (''And then if a patient gets it in the portal, which in our portal is simple, they just go on if they have it, they can download it. They don't actually need to provide a signature. So we send a note asking for a signature, and we never get those returned because the patient doesn't have to. And the modules aren't set up in the EMR to be compliant with that. So they get a notification. If they happen to send it back, of course they have to print it, sign it, scan it, and then figure out how to upload it into the portal. And then the staff have to actually take it from the portal and put it into the right record so that it can be retained.'').

[210] Prescribers are also not required to obtain signed confirmations for contact lens prescriptions that are delivered digitally, provided the prescriber complied with the CLR's requirement for obtaining and storing a record of a patient's verifiable affirmative consent to digital delivery. 16 CFR 315.3(c)(1)(i)(D). Instead, the prescriber need only retain evidence that the prescription was sent, received, or made accessible, downloadable, and printable—evidence that will typically be electronic and automatic via the email, text, or portal method used by the prescriber. *Id.*

[211] *See* section III, *infra.*

[212] Anonymous (NPRM Comment #0006) (''We already have a record of the prescription on file for the patient and most EHRs track when they are printed out.''); Lovejoy (WS Transcript at 10) (the requirement, as proposed, ''sounds like it would not be difficult to have a record of the patient receiving access to their prescription through [the] portal, so that would not seem like a significant burden.'').

[213] Lovejoy (WS Transcript at 10).

[214] Beatty (WS Transcript at 43) (''So if a portal could possibly be confusing, having a website where the patient can enter rudimentary data and then get back just the prescription information that they were looking for should be acceptable too.'').

[215] Montaquila (WS Transcript at 23) (''[The electronic] approach is not without challenges. The method requires many steps and a secure system for data transmission. Additionally, some electronic health record systems cannot automatically transmit the eyeglass or contact lens prescription to the patient portal. So when a patient requests an electronic copy of their prescription in those scenarios, the doctor must first print the prescription, attach it to an email, and then send it to the patient. For storage, it is possible to attach the information to the patient's medical record, but colleagues report that some electronic health record systems impose costs to store data over time. So using this method for them would increase the doctor's cost in perpetuity.'').

[216] 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. 21st Century Cures Act, Public Law 114–255, Title IV (2016). The Cures Act Final Rule, promulgated by the U.S. Dep't of Health & Human Servs., ONC, requires healthcare providers to enable patient access to enumerated classes of data in their electronic health record systems. ONC, 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program, Final Rule, 85 FR 25642 (May 1, 2020). These data classes include providers' clinical notes and information on medications, and the ONC noted in the latest update (Version 4 from July 2023) to the United States Core Data for Interoperability (USCDI) that the definition of ''clinical tests'' includes ''visual acuity exam.'' ONC, *HealthIT.gov,* Interoperability Standards Advisory (ISA), Clinical Tests, USCDI V4, *https://www.healthit.gov/isa/uscdi-data-class/clinical-tests#uscdi-v4.* While this decision may result in consumers having greater access to their prescription information in their EHRs, it does not directly impact prescribers' obligations for automatic prescription release under the Eyeglass Rule.

[217] Brown (WS Transcript at 7) (''it is very concerning that patients might not understand how to access their prescriptions. It's wonderful that patients are . . . requesting or desiring these prescriptions to be available to them online. But from the Prevent Blindness perspective and the patient's perspective, not every single patient is the same. Not everybody has the same access. Not everybody has the same broadband capabilities, the same smartphone technologies. And a lot of patients lack health literacy that encourages us as a completely available use to, or available avenue for them to receive access to their prescriptions.''); Aceto (WS Transcript at 42) (''My only concern with [technology] is not everybody, as we talked about with different clientele and different patients and different modalities, not everybody's as well versed.''); Hyder (WS Transcript at 45) (''ophthalmology patients who are older[—for the] digital option, they may not even want or have any idea of how to access [it].'').

[218] Brown (WS Transcript at 7) (''So it is encouraging, but it seems [] that there's a missed opportunity if patients can access their records digitally, but if they're not also given other means to access their prescriptions.''); Beatty (WS Transcript at 42) (''And so we'd want to be able to provide the possibility of delivering [prescriptions] electronically, but also allow for the provider to have the choice of how the electronic delivery would occur. And then the patient to consent to whether they want that electronic delivery or if they would prefer to have a paper version.'').

[219] Montaquila (WS Transcript at 26) (Once the prescription is on the portal, ''we have to then teach them, if they want to use the portal, how to find it. They have to go in, they have to log in, they have to download it. It's not that difficult to do, but they still need the education as you would for any new system you'd use. But then we have plenty of patients who say, 'I'm not electronic, just give me a copy.' '').

[220] Aceto (WS Transcript at 45) (''I will say that a good amount of the time that we spend oftentimes as opticians is sometimes calling for verification. But I do worry that some of these other burdensome regulations like the affirmative consent, for example, isn't going to change that. Because if [patients] forget [the prescription] at home, if they don't have it, we end up calling. And I don't know that it's that much of a burden to [prescribers]. Because as we've called optometrist's office and ophthalmologist's office, I will tell you that without fail because of the great work of the FTC since 1978, there hasn't been as much pushback as before those rules were instigated.''); Beatty (WS Transcript at 46) (''I think that the number of patients who are issued a paper prescription only, to just not have it when they need it is relatively high. And so a simple request from the patient to have a paper copy should they need one I think is a really simple request on their side and not really burdensome. I think that as long as that prescription is issued at the request and there's an electronic version available to that patient, then it should be ample.'').

[221] The Commission notes that for some telemedicine exams, digital delivery might be the only practical way for a prescriber to transmit the prescription immediately after the exam; in such cases, medical practices may need to obtain patient consent during the intake process. If a patient is in a medical office, however, and only the prescriber is remote, the office could print a paper copy

of the prescription for the patient. *See* Lovejoy (WS Transcript at 45) (''And more and more we're seeing some of those prescriptions being written after a telemedicine eye exam where the doctor and the patient are in a real time communication, but the doctor's remote. And the only way for the doctor to prescribe and get the prescription to the patient is electronically. It can be then printed out at the office and the patient can use it either there at the location or take it someplace else, but the patient then has access to it electronically as well.'').

[222] *See* section II.C., *supra.*

[223] CLR Final Rule, 85 FR 50683.

[224] *See* section VIII.A, *infra.*

[225] The digital delivery provision also does 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.

[226] 45 CFR 164.520; AOA (WS Comment #0047 submitted by Benner) (''Greater analysis of the overall burden [of] regulations on doctors would also be helpful to inform how best to streamline rule changes and explore alternative options, FTC could consider mirroring some of the acknowledgement requirements after the Department of Health and Human Services (HHS) Notice of Privacy Practices which does not require acknowledgment to be obtained at every visit. Seeking authorization to provide a prescription electronically could follow the same approach.'').

[227] Montaquila (WS Transcript at 35) (Allowing the consent form to be signed once ''would make it much easier for all of us to implement because we could educate [the patient] as to what the office policy is, whether that's paper or electronic or a combination thereof. It could happen at the outset when they first establish their relationship with us and only if we change policy or they make a request, because the patients could understand, 'I know your policy and I'm happy with it.' Or, 'I'm not happy with it, I want it done a different way.' And that could all be documented when we first meet them or at any time at [a] time [of] their choosing. So putting it in the patient's hands to have control.'').

[228] *See, e.g.,* 45 CFR 164.520(c)(1)(ii) (''No less frequently than once every three years, the health plan must notify individuals then covered by the plan of the availability of the notice and how to obtain the notice.'').

[229] For example, consider an instance where a prescriber obtains a patient's affirmative consent to digital prescription delivery via email in September 2024, and the prescriber relies on that consent to email prescriptions until and including the patient's September 2028 appointment. In 2029 the prescriber changes the digital delivery policy to delivery via patient portal, and the consumer signs a new affirmative consent during their annual 2029 appointment. The prescriber's office should retain the original affirmative consent to email delivery at least through September 2031 (September 2028 appointment plus three years), and should retain the 2029 consent to delivery via portal for three years, or for as long as the prescriber relies on that consent to provide prescriptions via portal, plus another three years.

[230] NPRM, 88 FR 268.

[231] CLR Final Rule, 85 FR 50682–50684; 16 CFR 315.2.

[232] *See* Office of the Federal Register, Regulatory Drafting Guide, Definitions, *https://www.archives.gov/federal-register/write/legal-docs/definitions.html* (''5. Do not include a substantive rule within a definition. A reader can easily miss a rule placed within a definition.'').

[233] Old Rule §§ 456.3, 456.4, and 456.5 are redesignated as new §§ 456.5, 456.6, and 456.7, respectively.

[234] 5 U.S.C. 553; 15 U.S.C. 57a(b)(1).

[235] *See* WS Transcript at 27–28, 36; Repka (WS Transcript at 28) (''The question [ ] was why the EMR companies haven't followed? Well, the new rule, it takes time to get a consumer base or a user base that goes and asks the big company to prioritize that development over 500 other development requests that they get. I think we clearly need one because a signature pad or a checkoff box, which just rolled out in Epic for procedure consents would make this easier.''); Montaquila (WS Transcript at 36) (''You mentioned Epic. I worked with one of the first Epic implementations in the country, believe it or not, way back. And they have a really good system with a signature pad. The system I use now has an iPad. You can open up, they can sign on the iPad. But I am talking to other colleagues who say that their EHR system has no option similar to this. All of them are probably moving in the same direction, right?'').

[236] *See, e.g.,* Repka (WS Transcript at 36) (''it still seems to me that the EMRs of the future will be able to accept this as an electronic signature, that it will store in some fashion other than necessarily on a paper that says any of the three things that you've had there. So that if there's an option to do that, it would be nice. If you still needed it to be on a printable PDF, then not as convenient.'').

[237] NAROC (NPRM Comment #0024 submitted by Neville). NAROC also requested the Commission be open to petitions from prescribers to allow additional digital methods of verifications as technology evolves and provided examples including the use of a personal identification number by the patient in an EHR, a fingerprint, a retinal scan, voice recognition or other verifiable consent documentation. WS Comment #0049 submitted by Neville. The FTC is open to new digital methods of verifications such as biometric data so long as the processes are optional, secure, there are methods in place to confirm and verify the identity of the signatory, and the signatures are designed such that they cannot be used by anyone other than their genuine owners.

[238] Montaquila (WS Transcript at 23) (''For the approach on screen, the consent is obtained on paper, but then other practices will use an electronic means to collect that signature.'').

[239] CLR NPRM, 81 FR 88535.

[240] CLR SNPRM, 84 FR 24667.

[241] NPRM, 88 FR 265.

[242] *See* sections I.D.4 *supra,* IV.C.3 *infra.*

[243] Although prescribers may similarly comply with the CLR by obtaining digital signatures, the Commission recognizes that, for the time being, the CLR will differ from the Eyeglass Rule by not expressly permitting signature collection in a digital format. The Commission can amend the CLR to include this express permission during its next rule review and, in the meantime, can provide clarity to prescribers through guidance materials.

[244] Press Release, Fed. Trade Comm'n, FTC Sends Cease and Desist Letters to Prescribers Regarding Potential Violations of the Commission's Contact Lens Rule (Feb. 21, 2023), *https://www.ftc.gov/news-events/news/press-releases/2023/02/ftc-sends-cease-desist-letters-prescribers-regarding-potential-violations-commissions-contact-lens*; Press Release, Fed. Trade Comm'n, FTC Sends 37 New Cease and Desist Letters Regarding Agency's Eyeglass Rule (Apr. 20, 2023), *https://www.ftc.gov/news-events/news/press-releases/2023/04/ftc-sends-37-new-cease-desist-letters-regarding-agencys-eyeglass-rule.*

[245] Botha (WS Transcript at 44).

[246] Beatty (WS Transcript at 44) (''While I think there are things that can be coupled together to decrease the amount of forms that a patient is having to sign, I do think that there are certain aspects of that intake process that should be separate so that we can make sure that the patient is acknowledging things appropriately . . . in this case, whether or not we separate the acknowledgement for the availability of the prescription.'').

[247] *See* section I.B, *supra.*

[248] Montaquila presentation, FTC Eyeglass Rule Workshop at 7, *https://www.ftc.gov/system/files/ftc_gov/pdf/Stephen-Montaquila-OD-Presentation.pdf.*

[249] *See* NPRM, 88 FR 286 (previously proposed as § 456.1(h)(2)).

[250] NPRM, 88 FR 265.

[251] The NPRM proposed to redesignate the provisions currently codified at §§ 456.3 through 456.5 as §§ 456.4 through 456.6, respectively, and add a new Section 456.3.

[252] *Id.* at 266.

[253] *Id.* at 280.

[254] *Id.* at 280–81.

[255] These comments are in addition to the comments detailed above on the need for automatic prescription release due to a lack of compliance and patient awareness of their rights to a prescription. *See* section II.A, *supra.*

[256] Williams (NPRM Comment #0002) (''This is a great idea and will protect patients!''); Wolin (NPRM Comment #0003) (''I support the proposed rule changes as a smart and efficient update''); Riffle (NPRM Comment #0013) (''I agree with the proposed rule''); Anonymous (NPRM Comment #0017) (''I support the proposal to require eye doctors to obtain signed confirmation of prescription release.'').

[257] NAROC also points out that more prescriptions in the hands of consumers might reduce the number of requests for additional copies. NPRM Comment #0024 submitted by Neville; WS Comment #0049 submitted by Neville.

[258] NAROC (NPRM Comment #0024 submitted by Neville; WS Comment #0049 submitted by Neville).

[259] NAROC (WS Comment #0049 submitted by Neville).

[260] Consumer Action (NPRM Comment #0026 submitted by McEldowney).

[261] NPRM Comment #0028 submitted by Sepp.

[262] 1–800 Contacts (NPRM Comment #0025 submitted by Montclair).

[263] *Id.* Another commenter stated that he approves of the Rule and hopes the Rule is enforced. White (NPRM Comment #0022).

[264] NAROC (NPRM Comment #0024 submitted by Neville). It encourages the Commission to report on how its access to prescribers' confirmation of prescription release has been used and whether it can demonstrate that the cost to prescribers associated with the confirmations is justified by improved enforcement. *Id.*

[265] WS Transcript at 32–33. *See also* Consumer Action (NPRM Comment #0026 submitted by McEldowney) (''In fact, providers should welcome this record-keeping as a way to prove that they are following the law if challenged.'').

[266] NAROC (WS Comment #0049 submitted by Neville).

[267] WS Transcript at 19.

[268] WS Comment #0049 submitted by Neville. *See also supra* note 174 (citing Lovejoy (WS Transcript at 19) noting the high percentage of optometrists' gross revenue that comes from the product sales)).

[269] NAROC (WS Comment #0049 submitted by Neville). Consumer Action does not believe it is a burden on prescribers to obtain, document, and retain a consumer's affirmative receipt of their prescription. NPRM Comment #0026 submitted by McEldowney.

[270] NAROC (WS Comment #0049 submitted by Neville). At the workshop, Joseph Neville said that he's been talking over the last two years with their members and they ''said they're not having problems [complying] with the Contact Lens Rule.'' WS Transcript at 28.

[271] WS Transcript at 31.

[272] National Taxpayers Union (WS Comment #0028).

[273] *Id.*

[274] *Id.* The Commission has not been able to replicate NTU's cost calculation. Based on NTU's estimate that a ''modest optometry establishment'' might conduct 3000 examinations per year, and using the NPRM burden estimate of 10 seconds to obtain a patient's confirmation and one minute to store it, the requirement would impose an additional paperwork burden on such a practice of 58.3 hours per year ($3{,}000 \times 70$ seconds $\div 60 \div 60$). Using the NPRM estimated wage rates for optometrists and office staff, such an additional burden would amount to an incremental burden of $1,439.88. However, staff does not know how accurate NTU's estimate for a ''modest optometry establishment'' is, and does not possess information about typical practices. As explained in this document's PRA section, staff based its ultimate burden calculations on the expected overall number of refractive exams that would result in a written prescription every year rather than trying to determine a number for a typical practice. *See* Paperwork Reduction Act, section VIII, *infra,* for an updated estimate for the amended Rule.

[275] WS Transcript at 40.

[276] NPRM Comment #0024 submitted by Neville.

[277] *Id.*

[278] Some of these comments were discussed above with respect to the Commission's determination that the failure to provide a prescription continues to be an unfair act or practice. *See* section II.A *supra.* One other commenter expressed disfavor with the proposal, but did not provide specific reasons for the opposition. Anonymous (NPRM Comment #0004).

[279] AOA (WS Comment #0047 submitted by Benner).

[280] AOA (WS Comment #0047 submitted by Benner). Appendix A to this comment contains a summary it created of the purported study results.

[281] AOA (WS Comment #0047 submitted by Benner). Similarly, at the workshop, Dr. Stivers suggested that most consumers sign papers at the doctor's office without reading them and questioned whether the confirmation of prescription release ''accomplish[es] anything in the broader context of all of the information that the patient is trying to absorb in that kind of environment.'' WS Transcript at 10.

[282] *See also* Stivers, WS Transcript at 11 (noting that regulations like the Eyeglass Rule require businesses to hire expensive attorneys and consultants to advise them, and the Commission should take into account the burden placed on ''the vast majority of practitioners or businesses in general that are absolutely law abiding.''

[283] *See* section VIII, *infra.*

[284] During the pendency of the Eyeglass Rulemaking, the American Optometric Association filed a comment in response to the Commission's Paperwork Reduction Act (''PRA'') notice for the Contact Lens Rule. That comment, CLR PRA Comment #0007 (submitted by Benner), is available at: *https://www.regulations.gov/comment/FTC-2023-0049-0007* (emphasis in original).

[285] AOA (NPRM Comment #0023 submitted by Benner; WS Comment #0047 submitted by Benner).

[286] Rosemore (WS Comment #0045) ''As an optometrist, the added requirements would be a significant burden on my practice . . . I'm not sure what sort of issue the Commission believes it is solving here.'' Dr. Rosemore added, ''I am disturbed that my profession continues to get treated like a punching bag. It appears to me that we are viewed by some at the Commission as predators to consumers instead of the doctors we are to our patients. I did nothing to deserve that treatment.'' Coast Eyes Pllc (WS Comment #0046) (''Nothing is broken here. Patients get their prescriptions without conflict. The financial/time/paper (material) burden on small business is not justified by the number of complaints.)''.

[287] Anonymous (NPRM Comment #0006) (''something that would take an immense amount of time and take away from patient care.''); Anonymous (NPRM Comment #0007) (isn't ''necessary'' and would be ''very time consuming.''); Cooper (NPRM Comment #0009) (''yet another example of an unnecessary, time consuming, and intrusive requirement [that would] add to cost of doing business which ultimately gets passed on to the patient (consumer)''); Anonymous (NPRM Comment #0011) (costly, time consuming, and redundant). WS Transcript at 23–24.

[288] Durkee (NPRM Comment #15).

[289] WS Transcript at 9. Voicing a similar concern, Dr. Montaquila said he's seen widespread confusion from patients as to why they are signing a prescription or confirmation of prescription release and he states that ''they don't understand the process.'' WS Transcript at 24. Dr. Masoudi raised communication issues surrounding the form when language barriers exist between the patient and staff. WS Transcript at 27.

[290] WS Transcript at 23.

[291] WS Transcript at 23–24.

[292] WS Transcript at 29.

[293] WS Transcript at 29.

[294] AAO (NPRM Comment #27).

[295] *Id.* The AAO recommended the Commission exempt from the confirmation-of-prescription-release amendment ophthalmology practices with fewer than ten full-time employees because they often operate with limited administrative support and may not use electronic health records. *Id.*

[296] WS Transcript at 31. Dr. Montaquila stated that he has not seen much difference since the Contact Lens Rule confirmation requirement was put in place andthat he'll give prescriptions whether or not there is a confirmation requirement in place.

[297] WS Transcript at 29.

[298] WS Transcript at 37–38.

[299] NPRM, 88 FR 287.

[300] NPRM, 88 FR 287.

[301] *Id.* at 281.

[302] The Commission has determined not to add an exemption for ophthalmology practices with fewer than ten full-time employees, as requested by the AAO. *See supra* note 295. It is equally important for patients at these practices to be aware of their right to receive their prescriptions and receive their prescriptions as it is for patients at larger practices. If the practices sell eyeglasses or have a direct or indirect financial interest in the sale of eyeglasses, they must comply with the confirmation-of-prescription-release amendments.

[303] WS Transcript at 34.

[304] WS Transcript at 34.

[305] Warby Parker (ANPR Comment #0817 submitted by Kumar) (bill of rights and signage); Tedesco (ANPR Comment #0042) (signage).

[306] AOA (NPRM Comment #0023 submitted by Benner); Masoudi (WS Transcript at 38) (suggesting that the FTC should be more active in making consumers more aware of their rights ''before they even walk in our door.''). Other commenters discussed a need for greater education generally in this area. *See* section VII.B, *infra.*

[307] NPRM Comment #0023 submitted by Benner. According to the AOA, these include: (1) online retailers cannot guarantee the glasses purchased will meet the consumers' visual needs; (2) if the eyeglasses do not fit well, the online retailer is not required to adjust the glasses in person, but will often instruct the consumer how to self-

adjust the glasses; and (3) the online retailer is not obligated to respond to any complaints or issues surrounding the purchase. *Id. See also* American Optometric Association, ''AOA: No letting up on Eyeglass Rule advocacy,'' Nov. 2, 2023, *https://www.aoa.org/news/advocacy/federal-advocacy/aoa-no-letting-up-on-eyeglass-rule-advocacy.*

[308] Durkee (NPRM Comment #15). At the workshop, panelist Pete Sepp of NTU inquired about the FTC not enforcing the Rule against prescribers who take actions aimed at improving automatic prescription release and suggested such actions be treated as ''safe harbors'' from FTC enforcement. One example he provided was for prescribers to show a training video to their employees on prescription release and retain evidence of the training. WS Transcript at 33. As explained in response, although every instance where a prescription is not automatically provided to a patient is a civil penalty violation, the Commission is generally not looking for one-off instances of non-compliance in its enforcement actions. *See* Bernstein (WS Transcript at 34). Nevertheless, the Commission does not believe expressly establishing ''safe harbors'' of the type described by Pete Sepp would sufficiently counter the significant non-compliance detailed elsewhere in this document.

[309] *See* section II, *supra.*

[310] *Id.*

[311] NPRM, 88 FR 263. This inquiry is particularly relevant in that, as the Commission has stated, it is primarily interested in bringing actions against repeat offenders, not prescribers who may make a one-off mistake in forgetting to release a prescription.

[312] *U.S.* v. *Doctors Eyecare Ctr., Inc.,* No. 3:96–cv–01224–D (N.D. Tex. June 24, 1996). The complaint alleged that the eye care center only released prescriptions when patients asked for them, and included waivers of liability on patients when doing so. The prescriber paid a $10,000 civil penalty and was enjoined from future violations of the Eyeglass Rule. *See* Press Release, Fed. Trade Comm'n, Dallas Eyecare Center Agrees to Settle Charges That They Failed to Give Consumers Copies of Their Eyeglass Prescriptions (May 3, 1996), *https://www.ftc.gov/news-events/press-releases/1996/05/dallas-eyecare-center-agrees-settle-charges-they-failed-give.*

[313] NAROC's comment mentions that, while a requirement for signage in the office was rejected as inadequate, industry members might use the option of making information easily available to customers in other formats, such as websites or point of sale handouts about patients' rights or prescriber responsibilities. NPRM Comment #0024 submitted by Neville. NAROC proffered these ideas as additive to, and not instead of, the confirmation proposal, which it supports. An anonymous commenter suggests that the FTC should educate the consumer and ''[m]aybe provide a template to the providers so that the consumer gets the same info, presented the same way at every provider?'' WS Comment #0037. It is unclear whether the commenter is suggesting this action in addition to, or instead of, the signed acknowledgment proposal. The Commission discusses business and consumer education as an additional method to increase business and consumer awareness of responsibilities and rights, respectively, in section VII.B, *infra.*

[314] NPRM, 88 FR 264 (signage), 263–64 (bill of rights).

[315] *See* CLR SNPRM, 84 FR 24675; Eyeglass I Rule, 43 FR 23998.

[316] NPRM, 88 FR 263.

[317] Commission staff first identified this issue in its Eyeglass II Report, where it explained that the automatic release requirement had not helped to prevent ''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 absent documentary evidence. Eyeglass II Report, *supra* note 14, at 275–76.

[318] *See* sections IV.C.2.a and VIII.A, *infra* (describing how many prescribers are using confirmation forms that contain extraneous information and thus, likely take far longer to read and sign than actually required under the rule).

[319] This calculation is based on estimates that there are 165 million eyeglass wearers who get exams every other year, and that there are 18,000 ophthalmologists and 43,000 optometrists in the United States. As discussed above, section I.D.5, *supra* note 67, this may undercount the number of optometrists, which could mean the per-provider burden is even less. On the other hand, the burden may fall differently on different providers (depending on their size, or volume, or electronic-records adoption, for instance), and at least one commenter, the National Taxpayers Union, felt it might be disproportionally felt by small providers. *See* section IV.B, *supra.*

[320] AOA (WS Comment #0047 submitted by Benner).

[321] *Id.*

[322] AOA's appendix A to its workshop comment (WS Comment #0047 submitted by Benner) does not contain information about the methodology of the survey or the representativeness of the surveyed population. This analysis assumes the methodology is sound and the population surveyed is appropriately representative—assumptions which may or may not be correct.

[323] Moreover, 28% of respondents disagree with the statement that the amount of paperwork they have to complete at a doctor's appointment is overwhelming (with another 25% responding neutrally) and 34% of respondents disagree with the statement that the complexity of the paperwork they have to complete at a doctor's appointment is overwhelming (with another 25% responding neutrally).

[324] However, the Commission notes that some of the burden that commenters suggest has resulted from the CLR confirmation-of-prescription-release requirement appears to be wrongfully attributed to that requirement. *See* sections IV.C.2.a, *infra,* and section VIII.A, *infra* (describing how in one form in use by many prescribers' offices, and recommended in the AOA's online toolkit for complying with the CLR, five out of six paragraphs are extraneous to the confirmation-of-prescription-release proposal).

[325] These options include permitting electronic delivery of eyeglass prescriptions, in which case prescribers would not need to request that the patient acknowledge receipt of the prescription. Yet, flexibility exists for prescribers who prefer to provide paper copies to their patients, as they do not need to offer an electronic option. *See* section III.C, *supra.* For instances in which a patient refuses to confirm prescription release, the prescriber shall note the patient's refusal on the document and sign it.

[326] *See* section III.C, *supra.*

[327] If multiple eyeglass prescriptions are provided on paper at the same time, the prescriber can obtain confirmation of prescription release with one signature, and need not obtain separate signatures for each prescription confirmation.

[328] To reduce the burden associated with prescription release, a prescriber could create a document requesting a single signature to confirm receipt of both an eyeglass and a contact lens prescription (in cases where both prescriptions are finalized at the same time). Such a document could meet the requirements of both rules so long as it is clear and conspicuous what the patient is signing for, and that the signature requested confirms receipt of *both* the contact lens and eyeglass prescriptions. Similarly, as mentioned above, a prescriber could use one document to obtain verifiable affirmative consent to digital prescription release of both contact lens and eyeglass prescriptions.

[329] NPRM, 88 FR 287.

[330] *Id.*

[331] 16 CFR 315.3(c)(3).

[332] *See* NPRM, 88 FR 260–61. The same purpose is stated for the exemption in the Contact Lens Rule. CLR Final Rule, 85 FR 50687.

[333] Current guidance issued by the Commission in connection with the Contact Lens Rule states the same. FTC, FAQs: Complying with the Contact Lens Rule, *https://www.ftc.gov/business-guidance/resources/faqs-complying-contact-lens-rule* (''If you're not sure if your interest qualifies, err on the side of caution and ask your patients to confirm receipt of their prescriptions.'').

[334] One commenter requested an exemption in long-term care settings for the confirmation requirement, as well as for affirmative consent for digital delivery. This commenter said that, in the long-term care setting, the parties responsible for the patients are almost never present during the exam and the patients themselves are not able to give consent and as a result, prescribers coordinate care with, and provide prescriptions to, facility staff. Morer (NPRM Comment #0021). In such situations, the Commission recommends the prescriber note in their records to whom the prescription was provided (*e.g.,* staff or caregiver), and whether it was provided on paper, or made available digitally and by what method. As with the instance where a patient refuses a copy of a prescription, *see supra* note 325,

the prescriber could relay that information to the Commission should questions about compliance arise.

[335] 16 CFR 315.3(c)(1) (CLR); NPRM, 88 FR 266.

[336] Montaquila (WS Transcript at 22). The Commission notes that other offices using EHRs could collect and store signatures electronically, as Dr. Montaquila noted they do for the consent to digital delivery. *Id.* at 23.

[337] Montaquila presentation, FTC Eyeglass Rule Workshop, *https://www.ftc.gov/system/files/ftc_gov/pdf/Stephen-Montaquila-OD-Presentation.pdf*.

[338] AOA, Contact Lens Rule Compliance Toolkit (July 2020), *https://www.aoa.org/AOA/Documents/doctor%20resources/Contact-Lens-Rule-Compliance-Toolkit.pdf*.

[339] WS Transcript at 22. Dr. Montaquila shared an example of a what the prescription pad looks like. *See* Montaquila presentation, FTC Eyeglass Rule Workshop, *https://www.ftc.gov/system/files/ftc_gov/pdf/Stephen-Montaquila-OD-Presentation.pdf*. This pad is also shown in the AOA's toolkit, with a note that doctors should contact the AOA Marketplace if interested in obtaining the product. *See* AOA, Contact Lens Rule Compliance Toolkit at 9 (July 2020), *https://www.aoa.org/AOA/Documents/doctor%20resources/Contact-Lens-Rule-Compliance-Toolkit.pdf*. At the bottom of each prescription sheet, after a statement in bright blue declaring, ''Contact lenses are medical devices which require ongoing medical care for optimal performance and safety. Please contact our office if you experience any signs of complications including pain, redness, loss of vision,'' there is a statement in black for patients to ''Sign below to indicate you were provided a copy of your contact lens prescription at the completion of your contact lens fitting,'' with a space for a signature and the date.

[340] WS Transcript at 22. Dr. Montaquila referenced *HealthIT.gov* data, as of 2021. *See* U.S. Dep't of Health & Human Servs., ONC, ''Office-based Physician Electronic Health Record Adoption,'' *https://www.healthit.gov/data/quickstats/office-based-physician-electronic-health-record-adoption*. The 88% figure, however, pertains to U.S. office-based physicians, but not specifically to optometrists or ophthalmologists. Moreover, this figure relates to adoption of EHR by doctors for their recordkeeping, but does not necessarily cover the use of EHR, and specifically portal-use, by patients themselves. There may be instances where doctors retain their records in electronic format but do not make them available via portal for their patients to access. And even when records are available electronically, many patients may opt not to use prescriber portals. *See* section III.B.1, *supra* (discussing patient portal access and usage) and section VIII.B.2, *infra* (discussing AOA survey of a small sample of optometrists showing that just 35% provided prescriptions electronically).

[341] WS Transcript at 22.

[342] WS Transcript at 22. Dr. Montaquila did not produce this study to staff. A news article on the study is available at: Cornell Chronicle, ''Study: E-prescribing cuts medication errors by seven-fold'' (2010), *https://news.cornell.edu/stories/2010/03/e-prescribing-cuts-medication-errors-seven-fold*.

[343] WS Transcript at 22.

[344] AOA (CLR PRA Comment #0007 submitted by Benner), *https://www.regulations.gov/comment/FTC-2023-0049-0007* (filed in response to FTC Request For Comment, 88 FR 55044 (Aug. 14, 2023), *https://www.regulations.gov/document/FTC-2023-0049-0001*). As discussed more fully in the PRA section of this document (section VIII, *infra* notes 452–55 and accompanying text.), the Commission has doubts about the methodology used for this survey,and does not rely on it for any determinations.

[345] WS Transcript at 22–23. Dr. Montaquila stated that EHR or practice management systems were not flexible enough to accommodate this functionality. *Id.*

[346] The Commission points out that if the prescriber delivers the prescription digitally, but the patient has not opted-in to the digital delivery option, the prescriber has not satisfied the requirements of § 456.2. *See* section III.B.1, *supra.*

[347] *See* Section VIII, *infra.*

[348] Section 456.4(a)(1)(ii) relating to digital prescription release, now cross references § 456.3, requiring verifiable affirmative consent to providing the prescription in digital format.

[349] *See* section III.B, *supra.*

[350] WS Transcript at 36.

[351] NPRM, 88 FR 265. *See* section III.C.3, *supra* notes 239–40 and text (citing Commission language from the CLR NPRM and CLR SNPRM supporting the position that, for the CLR, prescribers may obtain a patient's signature either on paper or digitally.).

[352] Although prescribers may similarly comply with the CLR by obtaining digital signatures, the Commission recognizes that, for the time being, the text of the CLR will differ from that of the Eyeglass Rule by not expressly permitting signature collection in a digital format. The Commission can amend the CLR to include this express permission during its next rule review and, in the meantime, can provide clarity to prescribers through guidance materials.

[353] 16 CFR 456.2(a).

[354] 16 CFR 315.4.

[355] 15 U.S.C. 7602.

[356] NPRM, 88 FR 271.

[357] *Id.* at 286.

[358] *Id.* at 281.

[359] NAROC (NPRM Comment #0024 submitted by Neville); NAROC (WS Comment #0049 submitted by Neville). NAROC noted, however, that it was not aware of significant instances in which prescribers had refused to automatically provide prescriptions until receiving payment from the insurance company. NAROC (NPRM Comment #0024 submitted by Neville); Lovejoy (WS Transcript at 48).

[360] NPRM Comment #0025 submitted by Montclair.

[361] NPRM Comment #0027 submitted by Repka.

[362] *Id.*

[363] WS Comment #0039. *See also* Hyder (WS Transcript at 47) (recommending that the FTC clarify the difference between covered services—such as eye health exams—and non-covered services—such as refractive exams—because ''insurance is complex and I think sometimes it can be a challenge to confirm whether or not the coverage is available for a patient.'').

[364] *See* section II.C, *supra.*

[365] Beatty (WS Transcript at 52); Lovejoy (WS Transcript at 52–53).

[366] Botha (WS Transcript at 53).

[367] However, prescribers who wait to collect payment for the examination until the eyeglass purchase is completed are precluded from using a confirmation method in which the statement confirming receipt of the prescription is included on the sales receipt.

[368] 16 CFR 456.1(b).

[369] 16 CFR 456.2(a).

[370] *See* AOA (ANPR Comment #0849 submitted by Peele); Brauer (ANPR Comment #0045); Yadon (ANPR Comment #0046); Bolenbaker (ANPR Comment #0633). Some of these commenters also stated that the defined term in the Rule is at odds with the definition of eye examination in the American Medical Association's Current Procedural Terminology codes to bill outpatient and office procedures, because that definition does not include a refraction. AOA (ANPR Comment #0849 submitted by Peele); Bolenbaker (ANPR Comment #0633).

[371] AOA (ANPR Comment #0849 submitted by Peele); Lunsford (ANPR Comment #0346); Bolenbaker (ANPR Comment #0633).

[372] Bolenbaker (ANPR Comment #0633).

[373] Lehman (ANPR Comment #0610).

[374] NPRM, 88 FR 279.

[375] NPRM, 88 FR 281.

[376] NPRM Comment #0025 submitted by Montclair.

[377] NPRM Comment #0028 submitted by Sepp.

[378] NPRM Comment #0024 submitted by Neville.

[379] *Id.*

[380] AAO (WS Comment #0027).

[381] *Id.*

[382] AOA (WS Comment #0047).

[383] NPRM Comment #0023 submitted by Benner (''The refractive error measured should be analyzed with other testing data, and an assessment of the patient's visual needs obtained during an in-person examination. This information is used to determine if, and in what amount, an optical correction is needed to provide optimal vision and comfort for all viewing distances.''); *see also* OAA (NPRM Comment #0020 submitted by Allen) (''A refraction may include objective and subjective assessment of the patient's refractive status; however, the results of a refraction do not provide all the information needed to determine an optical prescription.''); AOA (WS Comment #0047 submitted by Benner) (''we believe that the market has significantly evolved . . . thereby negating the need for any language adjustments in the rule. We believe the original language should stand without revision.'').

[384] AOA (WS Comment #0047 submitted by Benner).

[385] Beatty (WS Transcript at 54).

[386] *Id.* at 55–56.

[387] Boatner (WS Comment #0036); *see also* Lovejoy (WS Transcript at 49) (describing a

scenario where an ophthalmologist may ''want to do a measure of whether or not there is a refractive error to help with the medical diagnosis, but may not want to write a prescription at the end of that because that's not what the chief complaint is about and they don't see a need for the patient to have a prescription for corrective eyewear.'').

[388] Boatner (WS Comment #0036); Beatty (WS Transcript at 49).

[389] Boatner (WS Comment #0036); Lovejoy (WS Transcript at 51, 56) (stating that an exemption for use of medical judgment to withhold the prescription should be written into the Rule).

[390] Boatner (WS Comment #0036); *see also* Hyder (WS Transcript at 50).

[391] 16 CFR 456.2(c).

[392] *See* Hyder (WS Transcript at 50) (noting that some ophthalmologists have reported having patients say, ''you're not allowed to charge me for my refraction,'' and opining, ''there needs to be something that states in the rule that refraction services are different than the cost of a prescription.'').

[393] Botha (WS Transcript at 49).

[394] The term has been revised in the following sections of the final rule: (1) Definitions, Section 456.1(a), (b), (d), (e) and (g); (2) Separation of examination and dispensing, § 456.2(a)(1) and (2) and (b) through (d); and (3) Confirmation of prescription release, § 456.4(a)(1).

[395] The Commission also makes clear that requirement to release prescriptions does not depend on how prescribers label their exams, and whether a prescriber charges a fee for that particular practice. The definition for the amended refractive eye exam terminology remains ''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.'' § 456.1(b). A prescriber who charged a patient only one fee—designated as for an eye health exam—but also performed an exam that determined the refractive condition of a person's eyes or the presence of any visual anomaly, is still required to automatically release the prescription upon completion of the exam. A prescriber is only permitted to not release a prescription automatically following a refractive exam if the prescriber makes a medical determination that the patient should not be given a prescription for eyeglasses.

[396] Workshop panelists who spoke on this issue were unanimous in agreeing that if a prescriber decides not to provide the prescription in their medical judgment, then it is appropriate that they do not sell eyewear to that patient. WS Transcript at 57.

[397] *See, e.g.,* ACLens, ''Measuring Pupillary Distance (PD),'' *https://www.aclens.com/measuring-pupillary-distance*.

[398] The Rule, as amended, defines a prescription as 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.'' 16 CFR 456.1(g). As of the date of the NPRM, only four States, Alaska, Kansas, Massachusetts, and New Mexico, required the inclusion of pupillary distance measurements on prescriptions. NPRM, 88 FR 273.

[399] NPRM, 88 FR 276–77.

[400] NPRM, 88 FR 276–77.

[401] NPRM, 88 FR 277.

[402] OAA (NPRM Comment #0020 submitted by Allen); AOA (NPRM Comment #0023 submitted by Benner).

[403] AOA (NPRM Comment #0023 submitted by Benner); *see* NPRM, 88 FR 276.

[404] NAROC (Comment #0024).

[405] OAA (NPRM Comment #0020 submitted by Allen).

[406] AAO (NPRM Comment #0027 submitted by Repka).

[407] AAO (NPRM Comment #0027 submitted by Repka). Others also expressed favor with the Commission's decision not to require pupillary distance on prescriptions. Anonymous (NPRM Comment #0012) (the only way to ensure accurate measurement is by having the patient try on the desired frame and it is impossible to determine segment height and optical center without fitting the frame on the patient's face and marking the lens center); Anonymous (WS Comment #0034) (requiring pupillary distance on prescriptions would be the ''absolute death of the optical industry'' and it would be unfair to ''require people who properly train their staff to freely give the expertise so the consumer can go to another provider that has no such staff and get glasses.'').

[408] *Eyeglasses.com* (WS Comment #0040).

[409] *Id. Eyeglasses.com* also stated that, for purchases of bifocal, trifocal, or progressive lenses, a segment height is required and that consumers should be able to get a segment height measurement from an optical professional so they can include it when ordering eyeglasses online. *Id.*

[410] 1–800 CONTACTS (NPRM Comment #0025 submitted by Montclair).

[411] *Id.*

[412] *Id.*

[413] This commenter urged the Commission to require prescribers to ask patients to confirm receipt of the PD measurement, in addition to receipt of the prescription. 1–800 CONTACTS (NPRM Comment #0025 submitted by Montclair).

[414] *Id.*

[415] Beckman (WS Comment #0041).

[416] *Id.* An unidentified commenter agreed, indicating that when the optometrist fails to measure and include pupillary distance measurements on the prescription, they are preventing the consumer from shopping around and discovering lower prices elsewhere. Anonymous (NPRM Comment #0010). Another consumer comment does not explicitly mention pupillary distance, but stated it is their right to receive all of their personal medical information, and states they have to go to other sellers to be able to afford eyeglasses. Crete (WS Comment #0035).

[417] *See* section I.C, *supra.*

[418] *See* NPRM, 88 FR 274.

[419] As explained in the NPRM, pupillary distance measuring systems vary in cost and precision, and ''if the Commission required prescribers to include pupillary distance measurements on prescriptions, it is unlikely that prescribers would use less expensive rulers and the like, but instead—for professional and liability reasons—would 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.'' 88 FR 276.

[420] The Commission recognizes that there is a tension between the fact that there are zero and low-cost methods to measure pupillary distance and the fact that prescribers claim providing the measurement requires expensive equipment and potential increases in staff. However, both things can be true. Consumers are able to ascertain serviceable pupillary distance measurements without expensive training and equipment, while medical professionals will likely want—and perhaps even feel professionally obligated—to provide a measurement that meets higher standards of technical precision.

[421] EyeBuyDirect, ''How to Measure Pupillary Distance (PD),'' *https://www.eyebuydirect.com/guides/how-to-measure-your-pd*.

[422] Zenni, ''Measure your pupillary distance (PD),'' *https://www.zennioptical.com/measuring-pd-infographic*. The Commission has not analyzed whether the various methods consumers may use to determine their pupillary distance, or whether sellers manufacturing eyeglasses in accordance with self-measured pupillary distances, are permitted in all jurisdictions. The Commission noted this in the NPRM, 88 FR 274, but did not receive any comments on this topic in response to the NPRM.

[423] The FTC has heard from consumers that they have been charged between $15 and $40 to obtain an in-person pupillary distance measurement.

[424] Bailer (ANPR Comment #0191); Emanuel (ANPR Comment #0282); Land (ANPR Comment #0311).

[425] ANPR Comment #0748 submitted by Cutler.

[426] NPRM, 88 FR 276.

[427] Because the Commission did not find adequate evidence of unfairness, it need not consider alternative ways to remedy that unfairness. Thus, it does not address seller 1–800 CONTACTS' alternate methods for providing pupillary distance to patients.

[428] WS Transcript at 38.

[429] WS Transcript at 4–6, 16.

[430] WS Transcript at 23–24.

[431] Anonymous (WS Comment #0037).

[432] NPRM Comment #0027 submitted by Repka.

[433] NPRM Comment #0024 submitted by Neville. In addition, at the workshop, Mr. Lovejoy stated that the FTC should give prescribers some guidance on how to educate their own customers and make sure the message is consistent throughout the industry. WS Transcript at 58.

[434] *See, e.g., https://www.ftc.gov/business-guidance/resources/complying-eyeglass-rule* (for prescribers); *https://consumer.ftc.gov/articles/buying-prescription-glasses-or-contact-lenses-your-rights* (for consumers); *https://www.ftc.gov/news-events/news/press-releases/2020/12/ftc-sends-28-warning-letters-regarding-agencys-eyeglass-rule* (press release); *https://consumer.ftc.gov/consumer-alerts/2020/12/ftc-warns-eye-care-prescribers-follow-law-or-else* (consumer

alert); *https://www.ftc.gov/business-guidance/blog/2023/04/required-action-after-refraction-ftc-staff-sends-cease-desist-letters-about-eyeglass-rule-compliance* (business guidance).

[435] 5 CFR 1320.8(b)(3)(vi).

[436] 16 CFR 456.4(a)(1).

[437] NPRM, 88 FR 283.

[438] *Id.* at 282–83.

[439] CLR Final Rule, 85 FR 50709. The estimates for the Contact Lens Rule's confirmation requirement were, in turn, based on a (1) survey of how long it took consumers to read a proposed Contact Lens Rule confirmation statement, and (2) previously approved burden estimates for a similar patient-acknowledgment requirement under HIPAA rules, found at 45 CFR 164.520(c)(2)(ii).

[440] 88 FR 284.

[441] Anonymous (NPRM Comment #0006).

[442] Anonymous (NPRM Comment #0007).

[443] AOA (NPRM Comment #0023). *See also* Rep. Williams, House Committee on Small Business (WS Comment #0044) (''The Committee fears that this rule will have a disproportionate impact on small businesses by adding redundant requirements to already understaffed practices.'').

[444] Michaels (WS Transcript at 9) (''I don't think that it's a burden to provide the prescription. Where I see the burden is to ask for paperwork, to say, 'Sign this piece of paper acknowledging that we've already given you a prescription.' There's a lot of time, effort, discussion around that. I think that that is something that is greatly underestimated in terms of how long it takes.''); AOA (WS Comment #0047 submitted by Benner).

[445] Coast Eyes Pllc (WS Comment #46).

[446] Montaquila (WS Transcript at 23–24). Dr. Montaquila did not break down his 4-minute estimate by task, so it is unclear how long he estimates it takes for a consumer to simply read and sign the confirmation statement, as opposed to the time it takes for his staff to print out the prescription and confirmation and store the patient confirmation as a record. In its NPRM, the Commission allowed a total of two minutes and 10 seconds for the entire process (one minute for prescribers to print out the prescription, 10 seconds for the confirmation signature, and an additional minute for staff to store the signed confirmation.).

[447] National Taxpayers Union (NPRM Comment #0028 submitted by Sepp).

[448] *See* section IV.B, *supra* note 274 and text. As noted previously, the Commission has not been able to replicate the NTU estimate. Accepting NTU's assumption that a small practice performs 3000 refractive eyeglass examinations per year, the confirmation requirement would add a paperwork burden of $1,439.88 for such a practice based on the proposal and PRA analysis applied in the NPRM, and an increased paperwork burden of $1,318.73 based on the amendment and PRA analysis of this Final Rule. While the AOA has stated that approximately 92% of optometry practices have fewer than 25 employees and average $826,612 in gross receipts per annum (AOA NPRM Comment #23), the Commission does not have information detailing how many refractive eyeglass examinations a typical practice performs—or even what a ''typical practice'' is and whether it is advisable to weigh the burden based on a typical practice experience—and finds it preferable to calculate the burden based on the overall number of eyeglass wearers in the United States, and the estimate that each wearer obtains a refractive eye exam for eyeglasses every two years.

[449] NAROC (NPRM Comment #0024 submitted by Neville); *see also* Consumer Action (NPRM Comment #0026 submitted by McEldowney) (''we do not believe it is a burden on providers to obtain, document, and retain a consumer's affirmative receipt of their prescription.'').

[450] Neville (WS Transcript at 28–29).

[451] Coast Eyes Pllc did not provide any evidence in support of its $18,000 estimate, and it is not clear where this calculation comes from.

[452] AOA (CLR PRA Comment #0007 submitted by Benner), *https://www.regulations.gov/comment/FTC-2023-0049-0007* (filed in response to FTC Request For Comment, 88 FR 55044 (Aug. 14, 2023), *https://www.regulations.gov/document/FTC-2023-0049-0001*).

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

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

[455] The Commission notes that while the AOA claims to represent some 50,000 optometric professionals, only 327 members responded to the AOA's invitation and completed the survey, which could indicate that many of those who self-selected and took part in the survey were those who have concerns about the confirmation requirement, while most other AOA members do not have such concerns. However, there could be other reasons for the relatively small number of prescribers (in proportion to the total membership) who responded, so the Commission will not draw inferences from the low response rate.

[456] 2023 CLR PRA, 88 FR 88079.

[457] *See* section IV.C.2.a, *supra,* discussing the AOA model form exhibited by Dr. Montaquila at the workshop. A copy of the model form is available at *https://www.aoa.org/AOA/Documents/doctor%20resources/Contact-Lens-Rule-Compliance-Toolkit.pdf*.

[458] *Id.*

[459] *Id.*

[460] Montaquila (WS Transcript at 23).

[461] The Commission has never subscribed to the belief that consumers will be greatly confused as to why they are signing a straightforward confirmation statement such as, ''My eye care professional provided me with a copy of my contact lens prescription at the completion of my contact lens fitting.'' The Commission's understanding is based on a common sense reading of the statement, but is also supported by a survey submitted during the Contact Lens Rule rulemaking showing that 90% of consumers responded they understood the proposed confirmation statement, and 94% responded that they had no follow-up questions. Laurence C. Baker, ''Analysis of Costs and Benefits of the FTC Proposed Patient Acknowledgment and Recordkeeping Amendment to the Contact Lens Rule,'' 13 (2017), *https://www.ftc.gov/system/files/summaries/initiatives/677/10192017_meeting_summary_from_mko_for_the_contact_lens_rule_rulemaking_proceeding.pdf*.

[462] The Commission recently made a similar revision to its estimate of the time required to obtain confirmation for the Contact Lens Rule, and the revised burden figures received clearance by the Office of Management and Budget. *See supra* note 454.

[463] Standards for Privacy of Individually Identifiable Health Information, Final Rule, 67 FR 53182, 53261 (Aug. 14, 2002) (implementing 45 CFR 164.520(c)(2)(ii)).

[464] *See* section I.D.5, *supra* note 73.

[465] The Commission relies on industry sources for its estimate that eyeglass wearers typically obtain one refractive eye exam every two years. *See, e.g.,* AOA, Excel and Jobson Medical Information, The State of the Optometric Profession: 2013, at 4, *https://www.reviewob.com/wp-content/uploads/2016/11/8-21-13stateofoptometryreport.pdf* (showing an average interval between exams of 25 months); AOA, Comprehensive Eye Exams, *https://www.aoa.org/healthy-eyes/caring-for-your-eyes/eye-exams?* (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)) (a term-length mirrored by a majority of States, *see* CLR NPRM, 81 FR 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. 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.

[466] *See, e.g.,* CLR SNPRM, 84 FR 24693 n.347.

[467] CLR Final Rule, 85 FR 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 24693; NPRM, 88 FR 282.

[468] *See supra* note 462–63 and accompanying text.

[469] In order to utilize § 456.4(a)(1)(ii) however, a prescriber must obtain and maintain records or evidence of affirmative consent by patients to electronic delivery of

their prescriptions. The burden to do so is included in the recordkeeping burden calculation of this PRA section.

[470] NPRM, 88 FR 283.

[471] AOA (CLR PRA Comment #0007 submitted by Benner).

[472] The survey found that approximately 57% said they used a separate signed confirmation form, 35% said they opted for digital delivery, 15% used a confirmation statement on a signed sales receipt, 27% used a confirmation statement on a signed prescription copy, and 9% selected ''other.'' As noted, prescribers were permitted to choose more than one option, so these percentages add up to more than 100%.

[473] Section 456.3(a)(3) also requires that in the event that a patient declines to sign a confirmation requested under paragraph (a)(1)(i) the prescriber must note the patient's refusal on the document and sign it. However, the Commission has no reason to believe that such notation should take any longer than for the patient to read and sign the document, so the Commission will maintain its calculation as if all confirmations requested under paragraph (a)(1)(i) require the same amount of time. It is worth noting that using the 82.5 million figure here is an overestimate by the Commission, since it does not deduct for the number of patients who visit a prescriber who does not have a direct or indirect financial interest in the sale of eye wear and would not be required to confirm receipt of prescriptions under Rule amendment § 456.4(c). However, staff does not currently possess information as to what number of prescribers will qualify for the exception in § 456.4(c), and so has assumed that all patients receiving a prescription will either sign a confirmation of prescription release or a consent to receive their prescription electronically every year.

[474] *See, e.g.,* 246 Mass. Code Regs. § 3.02 (requiring optometrists to maintain patient records for at least seven years); Wash. Admin. Code § 246–851–290 (requiring optometrists to maintain records of eye exams and prescriptions for at least five years); Iowa Admin. Code r. 645–182.2(2) (requiring optometrists to maintain patient records for at least five years).

[475] 20,625,000 prescriptions (82.5 million prescriptions × 25%). As noted in section III.C., *supra,* prescribers may not need to obtain patient consents at every visit. But the Commission does not have reliable information as to the percentage of consumers that are new to their prescribers as opposed to being repeat visitors or how often prescribers' practices with digital prescription delivery will change and require new consents, and thus how many will or will not have to sign a consent-to-electronic-delivery. Thus, the Commission will assume, for PRA calculation purposes, that every time a consumer receives a digital prescription, the prescriber's staff has collected a signed consent. This very likely results in a significant overestimation of the consent burden.

[476] 20,625,000 prescriptions yearly × 20 seconds/60 secs/60 mins.

[477] 20,625,000 affirmative consents × one minute/60 mins) for storing such records.

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

[479] Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment Statistics, *https://www.bls.gov/news.release/ocwage.t01.htm.*

[480] Based on information that there are approximately 61,000 optometrists and ophthalmologists in the United States, this averages to $629 per prescriber per year.

[481] The Vision Council, Market inSights 2022. Total market value of eyeglass frames and lenses. Does not include exams, reading glasses, or contact lenses. The $149,691,431 cost of the Eyeglass Rule is 0.0042 of the total $35.6 billion market value.

[482] It is possible that bringing the prescription confirmation requirements for eyeglass prescriptions into conformity with those for contact lenses will ease staff training burdens rather than increase them, since prescribers' staff will not have to learn to differentiate between the two types and treat them differently for rule purposes.

[483] As explained in the PRA Section, *supra,* the Commission calculates an incremental burden of $38,389,993 from adding the confirmation of prescription release to the Eyeglass Rule. The Commission need not issue a final regulatory analysis under section 22 of the FTC Act because this amount does not meet the threshold of an annual effect on the national economy from the amendment of $100 million or more or cause the other changes or effects described in section 22(a)(1)(B) and (C). *See* 15 U.S.C. 57b–3.

[484] NAROC (WS Comment #0049 submitted by Neville).

[485] *See* section VIII, *supra.*

[486] See 13 CFR 121.201 (Small Business Size Regulations).

[487] *See* NPRM, 88 FR 285.

[488] AOA (NPRM Comment #0023 submitted by Benner).

[489] According to one publication, 65% 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://reviewob.com/wp-content/uploads/2016/11/8-21-13stateofoptometryreport.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.*

[490] NPRM, 88 FR 264.

[491] *Id.* at 263.

[492] NPRM, 88 FR 287.

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