

FEDERAL TRADE COMMISSION**16 CFR Part 456****[RIN 3084-AA80]****Ophthalmic Practice Rules****AGENCY:** Federal Trade Commission.**ACTION:** Final rule.

SUMMARY: The Federal Trade Commission ("FTC" or "Commission") has completed its regulatory review of the Ophthalmic Practice Rules ("Rules"), which require, among other things, that eye care practitioners provide patients with a copy of their eyeglass prescription upon completion of an eye examination. Pursuant to this review, the Commission has determined to retain the Rules in their current form. This document discusses the comments received in response to the Commission's request for public comment, analyzes the effect of the enactment of the Fairness to Contact Lens Consumers Act, 15 U.S.C. 7601–7610, and announces the Commission's decision to retain the Rules.

EFFECTIVE DATE: February 4, 2004.

FOR FURTHER INFORMATION CONTACT: Kial Young, (202) 326–3525, Federal Trade Commission, Bureau of Consumer Protection, Division of Advertising Practices, 601 Pennsylvania Avenue, NW., Washington, DC 20580.

SUPPLEMENTARY INFORMATION:**I. Introduction**

As part of its systematic review of its Rules and Guides to determine their effectiveness and impact, the Commission published a request for public comment in the **Federal Register** on April 3, 1997, seeking comments about the overall costs and benefits of the Ophthalmic Practice Rules and related questions.¹ The Commission received comments from numerous parties, including: (1) Associations representing various segments of the industry and professions, including the American Optometric Association, the Opticians Association of America, the National Association of Optometrists and Opticians, the American Academy of Ophthalmology, individual professionals, and mail-order sellers of contact lenses; (2) state attorneys general, state optometry boards, and a United States Congressman; and (3) consumers.²

¹ Request for Public Comments, 62 FR 15865 (Apr. 3, 1997).

² The comments have been filed on the Commission's public record as Document Nos. B21940700001, B21940700002, *et seq.* The comments are cited in this document by the name

In general, the comments primarily addressed two broad issues: (1) Whether the current Rules, which require the release of eyeglass prescriptions to patients upon completion of an eye examination, should be retained, repealed, or modified; and (2) whether the Rules' eyeglass prescription release requirement ("eyeglass prescription release rule") should be extended to require the release of contact lens prescriptions.

With respect to the first issue, the Commission has determined to retain the Rules in their current form. As to the second issue, while the Commission's regulatory review was pending, Congress enacted and the President signed the Fairness to Contact Lens Consumers Act, which requires that prescribers release contact lens prescriptions to their patients. The FTC is publishing a Notice of Proposed Rulemaking today seeking comment on a proposed rule to implement the Act, including a contact lens prescription release requirement. Accordingly, the Commission concludes that it is not necessary to address during this regulatory review whether to extend the Ophthalmic Practice Rules to mandate that contact lens prescriptions be released.

This document first describes the requirements and the background of the current Ophthalmic Practice Rules. It then summarizes the comments received regarding whether the eyeglass prescription release rule should be retained, eliminated, or changed, and explains the Commission's determination to retain that rule in its present form. Finally, this document discusses additional issues relating to this regulatory review of the Rules.

II. Description and Background of Ophthalmic Practice Rules

The Ophthalmic Practice Rules require an eye care practitioner (an optometrist or ophthalmologist) to provide a patient, immediately after completion of an eye examination, with a free copy of his or her eyeglass prescription (the "eyeglass prescription release rule"). The Rules also prohibit an eye care practitioner from conditioning the availability of an eye examination on a requirement that the patient agree to purchase ophthalmic goods from the practitioner. The Rules further prohibit an eye care practitioner

of the commenter, a shortened version of the comment number (the last one to three digits), and the relevant page(s) or attachments of the comment. All written comments submitted are available for public inspection at the Public Reference Room, Room 130, Federal Trade Commission, 600 Pennsylvania Ave., NW., Washington, DC 20580.

from making certain disclaimers and waivers of liability.

In promulgating the original Rules in 1978, the Commission found that many consumers were being deterred from comparison shopping for eyeglasses because eye care practitioners refused to release prescriptions, even when requested to do so, or charged an additional fee for the release of a prescription.³ At that time, prohibitions and restrictions on advertising of ophthalmic goods and services were commonplace. Indeed, eye care practitioner advertising, especially price advertising, was restricted in 49 states, either by governmental or private regulation.⁴ Without such advertising, consumers generally knew little about their options in purchasing eye exams and eyeglasses, including that they have the option of purchasing them separately. The Rules therefore include a requirement that eye care practitioners automatically release a copy of the prescription regardless of whether the patient requests it.⁵

The Commission previously has considered modifying the eyeglasses prescription release rule. In 1985, the agency published a notice of proposed rulemaking that invited comments on whether the rule should be modified or repealed.⁶ In 1989, the FTC decided to retain the rule, because there was still significant non-compliance with the rule and a continued lack of consumer awareness about their ability to obtain their prescription and purchase eyeglasses separately.⁷

III. Eyeglass Prescription Release Rule**A. Summary of Comments****1. Costs and Benefits of Eyeglass Prescription Release Rule**

In connection with the Commission's review of its Ophthalmic Practices Rules, the April 1997 **Federal Register** Notice requested comments on whether the eyeglass prescription release rule should be retained, modified, or eliminated. Many commenters support retention of that requirement, including

³ Advertising of Ophthalmic Goods and Services, Statement of Basis and Purpose and Final Trade Regulation Rule, 43 FR 23992, 23998 (June 2, 1978) (hereinafter "1978 Statement of Basis and Purpose").

⁴ *Id.* at 23994.

⁵ Ophthalmic Practice Rules, Final Trade Regulation Rule, 54 FR 10285, 10299, 10303 (Mar. 13, 1989) (hereinafter "1989 Statement of Basis and Purpose") (citing Ophthalmic Practice Rules: State Restrictions on Commercial Practice, Oct. 1986, at 251–52).

⁶ Ophthalmic Practice Rules; Proposed Trade Regulation Rule; Notice of Proposed Rulemaking, 50 FR 598, 602–603 (Jan. 4, 1985).

⁷ 1989 Statement of Basis and Purpose, *supra* note 5, 54 FR at 10303.

the attorneys general of 18 states ("State Attorneys General"),⁸ the National Association of Optometrists and Opticians ("NAOO") (a trade association whose members include many large chain optical firms),⁹ Opticians Association of America ("OAA"),¹⁰ Opticians Association of Georgia ("OAG"),¹¹ individual opticians,¹² the Illinois Association of Ophthalmology,¹³ and mail-order sellers of contact lenses, including 1-800 Contacts¹⁴ and Lens Express.¹⁵ Many consumers also filed comments in support of the eyeglass prescription release rule.¹⁶ These commenters generally argue that the rule continues to benefit consumers by allowing them to purchase eyeglasses from sellers other than their eye care practitioner, thereby increasing competition among eyeglass sellers and lowering the price of eyeglasses. The comments also state that the cost to eye care practitioners of providing an eyeglass prescription to their patients is minimal.¹⁷

For example, the NAOO contends that the rule has "contributed immensely to creating a pro-consumer, pro-competitive environment in much of the eyewear sector today, generating not only lower prices for all consumers, but enormous product, technological, managerial and service innovations as well."¹⁸ Similarly, the State Attorneys General said that the rule has provided consumers with a wide variety of alternative suppliers at varying price points and service levels, and has saved

consumers money.¹⁹ Supporters of retaining the rule also argue that lower prices have resulted in increased accessibility to eyewear.²⁰ Other commenters, including consumers, expressed similar views.²¹

On the other hand, the American Optometric Association ("AOA"),²² the California Optometric Association ("COA"),²³ the Texas Optometry Board,²⁴ and others urge the Commission to rescind the eyeglass prescription release rule. According to these commenters, increased competition and advertising in the eyecare marketplace now enable consumers to shop among a wide variety of eyeglass sellers, and have made consumers aware of the benefit to them of obtaining their eyeglass prescriptions.²⁵ These commenters further contend that giving a prescription to a patient who does not want one imposes unnecessary costs on eye care practitioners, such as preparing unnecessary paperwork and expending their time.²⁶

2. Release Upon Request

The request for public comment also asked whether, if the eyeglass prescription release rule is retained, the Commission should modify the rule to require an eye care practitioner to release a prescription only if the patient requests it, rather than releasing it automatically.

Most commenters who support retention of the eyeglass prescription release rule also urge the Commission to retain the requirement that the prescription be released automatically. Commenters, such as OAA and Lens Express, assert that many consumers still are not aware that they can obtain their eyeglass prescription.²⁷ OAA cites its 1997 survey showing that 68.5% of consumers are not aware of the Commission's eyeglass prescription release rule.²⁸ In addition, some consumers filed comments stating that

they did not request their eyeglass prescription from their eye care practitioners because they did not know they were entitled to it.²⁹

Commenters such as OAA also assert that, absent the automatic release requirement, consumers may be intimidated or coerced by their eye care practitioner into not requesting their prescription.³⁰ OAA further asserts that more ophthalmologists are now dispensing eyewear, and that many consumers are intimidated if a doctor says that you should buy eyewear from him or her.³¹

Several commenters also contend that there is still significant non-compliance with the rule by eye care practitioners,³² especially the automatic release requirement.³³ OAA cites a survey conducted in March 1997 that showed, according to OAA, that 29.3% of patients did not receive their prescriptions and 10.1% were refused their prescriptions when they requested them.³⁴ In addition, anecdotal evidence in the record claims that the overwhelming majority of eye doctors who dispense eyewear do not automatically give patients their eyeglass prescriptions.³⁵

By contrast, commenters who argue for repeal of the eyeglass prescription release rule generally also urge the agency to adopt an "upon request" standard if the rule is retained. According to AOA, many, if not most, patients want to purchase their eyeglasses from the eye care practitioners providing their eye

⁸ Attorneys General, #118. The comment was submitted by the Attorneys General of Alaska, Arizona, Arkansas, California, Connecticut, Delaware, Florida, Illinois, Iowa, Maryland, Michigan, Minnesota, New York, Ohio, Pennsylvania, West Virginia and Wisconsin. The Attorney General of Nevada subsequently sent a letter joining the other states in this comment.

⁹ NAOO, #119.

¹⁰ OAA, #120. The National Academy of Opticianry also filed a comment, #115, stating that it supports the positions taken by Opticians Association of America.

¹¹ OAG, #60. See also Society of Dispensing Opticians of Kentucky, #28. Many individual opticians filed comments substantially similar to the OAG comment. See, e.g., E. Carter, #45; D. Drake, #55; All About Vision Center, #56; S. Sanford, #62; Oldham's Opticians, #65; Price and Wood Opticians, #72.

¹² See, e.g., H. Moyer, #9; Optical Fashions, #75; Professional Opticians, #31.

¹³ Illinois Association of Ophthalmology, #66 at 1-2.

¹⁴ 1-800 Contacts, #70 at 1.

¹⁵ Lens Express, #113 at 3-4.

¹⁶ See, e.g., A. King, #2; C. Bentley, #5; N. Fraby, #6; P. Guidoni, #12; J. Ruffino, #14; D. Murphy, #16; M. Walker, #17; C. Walker, #18; A. McKinley, #19; A. Cantrell, #21; T. Block, #22; B. Madewell, #23; T. Yancy, #24; E. Sharp, #43; K. Kinsey, #53.

¹⁷ See, e.g., NAOO, #119 at 9; OAA, #120 at 4; Illinois Association of Ophthalmology, #66 at 2.

¹⁸ NAOO, #119 at 8-9 (quoting Regina Herzlinger, Market-Driven Health Care (1997)).

¹⁹ Attorneys General, #118, at 2, 6.

²⁰ NAOO, #119 at 7-9. Other commenters agreed. See, e.g., 1-800 Contacts, #70 at 2.

²¹ See, e.g., Lens Express, #113 at 6; OAA, #120 at 1; G. Gac, #4 (consumer freedom of choice); D. Ingraham, #44 (same); W. Schaap, #3 (same); J. Lamet, #1 (price competition); E. Bode, #25 (same); F. Bassett, #7 (lack of awareness of right to obtain prescription); N. Simonetti, #13 (same); consumer #15 (consumer right to prescription); E. Bode, #25 (same).

²² AOA, #111.

²³ COA, #112, at 1-2.

²⁴ Texas Optometry Board, #122.

²⁵ AOA, #111 at 1-2; COA, #112 at 4.

²⁶ COA, #112 at 7.

²⁷ OAA, #120 at 9-10; Lens Express, #113 at 7.

²⁸ OAA, #120 at 9-10. The survey asked consumers: "Previous to reading this form were you aware of the Prescription Release Rule?"

²⁹ See, e.g., F. Bassett, #7; N. Simonetti, #13; see also K. Kinsey, #53 (many consumers, especially the elderly, do not know they can shop around).

³⁰ OAA, #120 at 1, 9.

³¹ *Id.* at 7-8.

³² See, e.g., OAA, #120 at 9.

³³ Lens Express, #113 at 4-5; OAA, #120 at 9. In addition, several consumers commented that they had not received their eyeglass prescription as required by the eyeglass prescription release rule. See, e.g., D. Ingraham, #44 (consumer unable to get copy of eyeglass prescription); J. Bassett, #7 (eye doctor did not release prescription until after he purchased eyeglasses; he did not ask); N. Simonetti, #13 (consumer has never been given prescription and did not ask because he did not know of his right to obtain prescription).

³⁴ OAA, #120 at 9. OAA did not provide any further details about the survey or its methodology.

³⁵ Paul Klein, O.D., "Forcing ODs to Release CL Prescription Does No Good," *Vision Monday*, Apr. 3, 1995, at 46, cited in Lens Express, #113 Exhibit 1.

Commenters raise some additional reasons for retaining the rule in its current form. For example, the OAA states that if the rule is cut back, many small opticians will go out of business. OAA, #120 at 11. OAA further notes that managed vision care and third-party insurance programs have encouraged one-stop shopping by locating dispensaries and practitioners in close proximity. These trends, OAA asserts, have limited opportunities for opticians and limited freedom of choice for consumers. OAA, #120 at 7-8.

examination, or from an affiliated optical chain. Commenters supporting this revision of the rule contend that patients generally are aware of their right to obtain their eyeglass prescriptions,³⁶ and that those who want their prescriptions routinely ask for and receive them. As such, these commenters argue, the automatic release of eyeglass prescriptions to all patients, including those who do not want them, is inefficient and wasteful.³⁷

One commenter, the Society for Excellence in Eyecare ("SEE"), a professional society of clinical ophthalmic surgeons, urged the Commission to modify the rule to require physicians to provide an eyeglass prescription only when appropriate in the physician's opinion or at the request of the patient. SEE suggests that many patients do not need a new prescription each time they visit an eye doctor because their prescription has not changed. According to SEE, giving patients a prescription under such circumstances probably leads many patients to believe that the prescription must be filled.³⁸

3. Overlap or Conflict With Other Laws

The request for public comment also asked for comments on whether the Ophthalmic Practice Rules overlap or conflict with other federal, state, or local laws or regulations. Several commenters respond that the eyeglass prescription release rule overlaps with or duplicates laws in some states, such as California and Texas, which already require the release of eyeglass prescriptions.³⁹ These commenters state that, at least as to those particular states, the existence of the state law makes the federal requirement unnecessary. OAA comments that optometric regulations in seven states conflict with the eyeglass prescription release rule's automatic release requirement by requiring the release of eyeglass prescriptions only upon the request of the patient. OAA further states that some of these state regulations make the prescription release contingent upon a patient's fulfillment of all financial obligations. Finally, OAA states that Oklahoma's optometric regulations are inconsistent

with the disclaimer provisions in the Rules.⁴⁰

B. Commission's Determinations Regarding Eyeglass Prescription Release Rule

The Commission has determined not to initiate a proceeding to repeal the eyeglass prescription release requirement. Some eye care practitioners may release prescriptions upon request in the absence of a federal release requirement. The evidence in the record, however, suggests that some eye care practitioners continue to refuse to release eyeglass prescriptions, even though this conduct has been unlawful under the Rules for nearly twenty-five years. If the eyeglass prescription release rule were eliminated, additional eye care practitioners might refuse to release eyeglass prescriptions so that they could receive the economic benefits from inducing patients to purchase both an eye exam and eyeglasses from them. Because release might not occur in the absence of a federal release requirement and because release of prescriptions enhances consumer choice at minimal compliance cost to eye care practitioners, the FTC has decided to retain the eyeglass prescription release rule.

The Commission also has decided not to commence a proceeding to modify the rule so that eye care practitioners are only required to release eyeglass prescriptions upon request. The comments submitted indicate that some consumers still are not aware of their right under the rule to obtain their eyeglass prescription from their eye care practitioner. In the absence of automatic release, these consumers may not know to ask for their prescription, or their eye care practitioner may discourage them from requesting it. With automatic release, these consumers will receive their prescription so that they can comparison shop among eyeglass sellers if they choose to do so. The record also shows that the burden on eye care practitioners in releasing prescriptions is minimal. Moreover, the recently enacted Fairness to Contact Lens Consumers Act provides for automatic release of contact lens prescriptions, and thus maintaining automatic release of eyeglass prescriptions provides consistency between the two release requirements. In light of all these factors, the FTC declines to start a proceeding to amend the rule to require release of eyeglass prescriptions only upon request.

Finally, the Commission concludes that the eyeglass prescription release

rule does not conflict with other laws. The rule does not conflict with the optometric regulations cited by OAA, because eye care practitioners can comply with both the federal and the state requirements. The state laws cited by OAA require eye care practitioners to release eyeglass prescriptions upon request. These laws do not prohibit eye care practitioners from automatically releasing eyeglass prescriptions, as required by the rule. Moreover, there is no information in the record that any states are interpreting their laws in such a way as to conflict with application of the federal requirements.⁴¹

C. Other Issues Related to Ophthalmic Practice Rules

1. Waivers and Disclaimers (16 CFR 456.2(d))

The request for public comment on the Ophthalmic Practice Rules also asked whether any changes should be made to the prohibition in Section 456.2(d) against the use of certain waivers or disclaimers of liability by eye care practitioners, or to the Commission's interpretation of that provision.⁴²

Section 456.2(d) prohibits eye care practitioners from placing on an eyeglass prescription, requiring a patient to sign, or delivering to a patient, any waiver or disclaimer of liability for the accuracy of the eye examination or the accuracy of the ophthalmic goods and services dispensed by another seller. Section 456.2(d) was originally promulgated because disclaimers "may have the effect of making consumers erroneously believe that other dispensers are not qualified to dispense their eyeglasses and discouraging consumers from shopping around."⁴³

Section 456.4 states that eye care practitioners are not liable under the Rules for the ophthalmic goods and services that another seller has dispensed. The FTC has interpreted Section 456.2(d) consistent with Section 456.4 to allow eye care practitioners to make truthful and non-misleading statements on prescriptions that sellers of ophthalmic goods and services are

³⁶ The Illinois Association of Ophthalmology, while supporting the rule as is, states that most consumers are aware that they are entitled to receive their eyeglass prescriptions. Illinois Association of Ophthalmology, #66 at 2.

³⁷ AOA, #111 at 2; COA, #112 at 2-3, 5.

³⁸ SEE, #82. SEE did not submit, however, and the record does not contain, any evidence indicating that automatic release of eyeglass prescriptions in fact leads consumers to fill their prescriptions unnecessarily, or otherwise causes consumer injury.

³⁹ See, e.g., COA, #112 at 3 (California); Texas Optometry Board, #122.

⁴⁰ OAA, #120 at 5-6.

⁴¹ The provision of the Oklahoma regulation that, according to OAA, violates the Rules' disclaimer provision, states that "the examining optometrist or physician shall not be responsible for the accuracy of the optical materials furnished by another person." As discussed in Part III.C.1., *infra*, this regulation does not conflict with any portion of the Commission's Rules.

⁴² The Federal Register Notice further specifically asked what problems, if any, the current requirement, or its interpretation, has caused, and how any such problems could be remedied.

⁴³ 1978 Statement of Basis and Purpose, *supra* note 3, 43 FR at 23998.

responsible for harm caused by the products they sell. For example, an eye care practitioner may state on a prescription that "the person who dispenses your eyeglasses is responsible for their accuracy." The eye care practitioner, however, may not include a waiver or disclaimer of its own liability along with such a statement.⁴⁴

COA requests that the Commission amend the Rules to allow disclaimers of liability for the accuracy of the ophthalmic goods and services dispensed by another seller.⁴⁵ COA contends that it is unlikely under state tort law that an eye care practitioner would be held liable for the negligence or breach of warranty of an independent third party who provided ophthalmic goods to the practitioner's patients. As such, COA asserts that a disclaimer of liability provides truthful and useful information to the patient, alerting the consumer to the possibility of a dispute concerning such liability.⁴⁶ The AOA similarly requests that the Rule be amended to permit eye care practitioners to include on prescriptions truthful and non-misleading disclaimers of liability for the actions of sellers of ophthalmic goods and services.

OAA also argues that the Rules should be amended to require that eye care practitioners affirmatively state that they are liable for errors in prescriptions even if another seller, such as an optician, fills the prescription. OAA believes that in the absence of such a statement, some eye care practitioners may mislead their patients into believing that the eye care practitioner will not be liable in these circumstances.⁴⁷ The OAG and several

opticians filed similar comments, stating that eye care practitioners often include statements on prescriptions implying that if a seller other than the eye care practitioner fills the prescription, the goods or services sold may be inferior. These commenters want the Rules revised to limit the statements made on prescriptions to prevent statements that imply that the goods or services that non-eye care practitioners sell are inferior.⁴⁸

The Commission has determined to retain Section 456.2(d) in its current form. No evidence was submitted that indicates that its restrictions on the use of disclaimers and waivers are no longer needed to prevent harm to consumers. In addition, because of its long-standing and consistent interpretation that the Rules allow eye care practitioners to make truthful and non-misleading statements that other sellers are liable for the harm their own products cause, it is not necessary to amend the Rules to explicitly permit such statements. Finally, the Commission believes that case-by-case law enforcement under section 5 of the FTC Act is a more effective means than rulemaking of addressing any false or misleading statements by eye care practitioners on prescriptions as to their liability for prescription errors or the quality of other sellers' goods and services.

2. Other Proposals

The OAA also recommends that the Commission amend the Ophthalmic Practice Rules to prohibit the use of expiration dates for eyeglass prescriptions, with exceptions for specific, well-defined medical reasons. OAA states that practitioners currently use arbitrarily determined and unjustifiable expiration dates, such as six months or one year, to deter

consumers from using their eyeglass prescriptions.⁴⁹

The Commission declines to initiate a proceeding seeking to amend the Rules to set expiration dates for eyeglass prescriptions. As explained above, the purpose of the Rules is to prohibit acts and practices that deter consumers from comparison shopping for eyeglasses. There is no evidence in the record that eye care practitioners are using expiration dates as a means of impeding the ability of consumers to purchase eyeglasses from other sellers or otherwise causing consumer injury. In the absence of such evidence, the Commission has decided not to consider setting expiration dates for eyeglass prescriptions.⁵⁰

IV. Conclusion

For the foregoing reasons, the Commission has determined to retain the Ophthalmic Practices Rules in their current form.

List of Subjects in 16 CFR Part 456

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

Authority: 15 U.S.C. 41–58.

By direction of the Commission.

Donald S. Clark,

Secretary.

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⁴⁹ OAA, #120 at 3–4.

⁵⁰ The Commission notes that Congress has established a minimum expiration date of one year for contact lens prescriptions, with an exception for cases in which medical reasons warrant a shorter time period. See 15 U.S.C. 7604. However, different considerations may apply to contact lenses than to eyeglasses, and, in any event, the record in this regulatory review does not indicate consumer injury that would support a rulemaking proceeding by the Commission to set an expiration date for eyeglass prescriptions.

⁴⁴ 1989 Statement of Basis and Purpose, *supra* note 5, 54 FR at 10299. The Commission's interpretation of this provision originally was set forth at 43 FR 46296–46297 (Oct. 6, 1978).

⁴⁵ COA, #112 at 6.

⁴⁶ COA, #112 at 6.

⁴⁷ OAA, #120 at 13. OAA does not address the point made by the AOA and COA.

⁴⁸ See, e.g., OAG, #60; E. Carter, #45; D. Drake, #55; All About Vision Center, #56; Price and Wood Opticians, #72.