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16 CFR Parts 315 and 456
Contact Lens Rule; Ophthalmic Practice Rules; Proposed Rule and Final Rule

FEDERAL TRADE COMMISSION

16 CFR Parts 315 and 456

RIN 3084–AA95

Contact Lens Rule; Ophthalmic Practice Rules

AGENCY: Federal Trade Commission.

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

SUMMARY: In this document, the Federal Trade Commission (the ''Commission'' or ''FTC'') issues a Notice of Proposed Rulemaking seeking comment on its proposed rule to implement the Fairness to Contact Lens Consumers Act (''the Act''), which provides for the availability of contact lens prescriptions to patients and the verification of contact lens prescriptions by prescribers. This document also proposes two clerical amendments to the Commission's Ophthalmic Practice Rules, which are designed to clarify the distinction between those Rules and the proposed Contact Lens Rule.

DATES: Public comments must be received on or before April 5, 2004.

ADDRESSES: Comments should refer to ''Contact Lens Rule, Project No. R411002.'' Comments filed in paper form should be mailed or delivered, as prescribed in the **SUPPLEMENTARY INFORMATION** section, to the following address: Federal Trade Commission/ Office of the Secretary, Room 159–H, (Annex A) 600 Pennsylvania Avenue, NW., Washington, DC 20580. Because paper mail in the Washington area and at the Agency is subject to delay, please consider submitting your comments via electronic mail. Comments filed in electronic form (except comments containing any confidential material) should be sent, as prescribed in the **SUPPLEMENTARY INFORMATION** section, to the following e-mail box: *contactlensrule@ftc.gov.* All Federal Government agency rulemaking initiatives are also available online at *http://www.regulations.gov.*

Comments on any proposed filing, recordkeeping, or disclosure requirements that are subject to paperwork burden review under the Paperwork Reduction Act should additionally be submitted to: Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10102, Washington, DC 20503, Attention: Desk Officer for Federal Trade Commission, as well as to the FTC Secretary at the address above.

FOR FURTHER INFORMATION CONTACT: Thomas Pahl or Kial Young, (202) 326–2738, *contactlensrule@ftc.gov,* Federal Trade Commission, Bureau of Consumer Protection, Division of Advertising Practices, 600 Pennsylvania Avenue, NW., Washington, DC 20580.

SUPPLEMENTARY INFORMATION:

I. Background

Fairness to Contact Lens Consumers Act

On December 6, 2003, President Bush signed the Fairness to Contact Lens Consumers Act (''the Act'').[1] Among other things, the Act requires that prescribers—such as optometrists and ophthalmologists—provide contact lens prescriptions to their patients upon the completion of a contact lens fitting.[2] The Act also mandates that prescribers verify contact lens prescriptions to third-party contact lens sellers who are authorized by consumers to seek such verification.[3] Further, the Act directs the Commission to conduct a study to examine the strength of competition in the sale of prescription contact lenses, including an examination of several specified issues.[4]

The Act directs the Commission to prescribe implementing rules.[5] Any violation of the Act or its implementing rules constitutes a violation of a rule under section 18 of the Federal Trade Commission Act, 15 U.S.C. 57a, regarding unfair or deceptive acts or practices.[6] The Act also authorizes the Commission to investigate and enforce the Act in the same manner, by the same means, and with the same jurisdiction, powers, and duties, as a trade regulation rule under the Federal Trade Commission Act.[7]

The Commission already enforces the Ophthalmic Practice Rules.[8] These Rules primarily require the release of eyeglass prescriptions to patients at the completion of an eye examination, and prohibit eye care practitioners from placing certain conditions on such release. The Commission today proposes two clerical amendments, set forth in sections III and XI below, to clarify the relationship between the Ophthalmic Practices Rules and the proposed rule under the Fairness to Contact Lens Consumers Act.

II. Overview of the Proposed Contact Lens Rule

Nearly 36 million Americans—almost 13% of all Americans—wear contact lenses.[9] The contact lens market in the United States is a multi-billion dollar market. There are numerous manufacturers of contact lenses and many different channels of distribution, including traditional eye care practitioners (*e.g.*, ophthalmologists and optometrists), national and regional optical chains, mass merchants (*e.g.*, Wal-Mart and Costco), and mail order and Internet firms.

The contact lens market has undergone significant change in recent years. The development of disposable soft contact lenses, followed by the growth of ''alternative'' retail sources of contact lenses (*e.g.*, non-eye care practitioners), including mail order and Internet firms, and mass merchants, has given consumers a greater choice of sellers and means of delivery when they purchase contact lenses. Such choice can have important benefits to consumers. Competition among contact lens sellers benefits consumers through lower prices, greater convenience, and improved product quality.

Key to consumer choice among contact lens sellers is the availability of the contact lens prescription. To this end, the proposed Rule is designed to implement the Act's specific provisions regarding the release and verification of contact lens prescriptions, and otherwise to further the Act's goals of ensuring the availability of such prescriptions so that consumers can choose among sellers when purchasing contact lenses. The proposed Rule tracks the language of the Act very closely:

- Section 315.1 describes the scope of the regulations under the Act.
- Section 315.2 sets forth definitions for the terms used in the proposed Rule.
- Section 315.3 requires prescribers to provide patients with a copy of their contact lens prescription immediately upon completion of a contact lens fitting, and to provide or verify contact lens prescriptions to any third party designated by a patient. This section further prohibits prescribers from placing certain conditions on the release or verification of a contact lens prescription.
- Section 315.4 limits the circumstances under which a provider can require payment for an eye exam prior to releasing a contact lens prescription to a patient.
- Section 315.5 requires contact lens sellers to either obtain a copy of a patient's prescription, or verify the

[1] 15 U.S.C. 7601–7610 (Pub. L. 108–164).

[2] *Id.* at 7601.

[3] *Id.* at 7601, 7603.

[4] *Id.* at 7609.

[5] *Id.* at 7607.

[6] *Id.* at 7608.

[7] *Id.*

[8] 16 CFR part 456.

[9] *See* Health Products Research (VIS)—Annual 2000 Year-End Consumer Contact Lens Survey (*cited in* ''Trends in Contact Lenses & Lens Care,'' The Bausch & Lomb Annual Report to Vision Care Professionals (Dec. 2001)).

prescription, before selling contact lenses, and sets forth procedures for obtaining such verification. This section also addresses the issue of private label contact lenses.

- Section 315.6 sets minimum expiration dates for contact lens prescriptions, with an exception for cases involving the prescriber's medical judgment with respect to a patient's ocular health.
- Section 315.7 prohibits certain specified parties from representing that contact lenses may be obtained without a prescription.
- Section 315.8 prohibits prescribers from using or requiring patients to sign any waiver or disclaimer of liability for the accuracy of an eye examination.
- Section 315.9 establishes that violations of the proposed Rule will be treated as violations of a rule defining an unfair or deceptive act or practice under the FTC Act.
- Section 315.10 addresses the proposed Rule's severability.

Following is an overview of the proposed Rule, with brief discussions where needed. The full text of the proposed Rule appears in section X of this document.

Section 315.1 Scope of Regulations

Part 315, which shall be called the ''Contact Lens Rule,'' implements the Fairness to Contact Lens Consumers Act, codified at 15 U.S.C. 7601–7610. The rules in part 315 of Title 16 of the Code of Federal Regulations address release and verification of contact lens prescriptions and related issues in implementing the Act. In contrast, the rules in part 456 of Title 16 (the ''Ophthalmic Practices Rules'' or ''Eyeglass Rule'') address the release of eyeglass prescriptions and related issues. See 16 CFR part 456.

Section 315.1 describes the basis for, and the general scope of, the regulations in part 315. It indicates that part 315 governs contact lens prescriptions and related issues, and clarifies that rules applicable to eyeglass prescriptions are found in part 456.

Section 315.2 Definitions

The Act states that a prescription is verified if, among other things, the prescriber fails to communicate with the seller within ''eight business hours, or a similar time as defined by [the FTC],'' after receiving proper verification information from the seller. Eight business hours'' is not expressly defined in the Act. The purpose of the time period, however, is to give prescribers an adequate period of time during normal office hours to act upon a prescription verification request, while at the same time allowing sellers to fill customer orders expeditiously.

Business hour is defined under the proposed Rule to mean an hour between 9 a.m. and 5 p.m., during a weekday (Monday through Friday), excluding Federal holidays. For purposes of section 315.5(c)(3), ''eight (8) business hours'' shall begin at the time that the seller provides the prescription verification request to the prescriber and conclude after eight (8) business hours have elapsed, except that the period for verification requests received during non-business hours shall begin at 9 a.m. on the next weekday that is not a Federal holiday.

A few examples may help clarify how eight business hours would be calculated under the proposed definition: (1) A response to a verification request received at 10:30 a.m. on Monday morning would be required by 10:30 a.m. on Tuesday morning; (2) a response to a verification request received at 10 p.m. on Monday night would be required by 9 a.m. on Wednesday morning, *i.e.*, eight business hours after the verification period commences at 9 a.m. on Tuesday morning; (3) a response to a verification request received at 2 p.m. on Saturday afternoon would be required by 9 a.m. on Tuesday morning, *i.e.*, eight business hours after the verification period begins at 9 a.m. on Monday morning; and (4) a response to a verification request received at 10:30 a.m. in the morning on Columbus Day (a Monday) would be required by 9 a.m. on Wednesday morning, *i.e.*, eight business hours after the verification period commenced at 9 a.m. on Tuesday morning.

Commission means the Federal Trade Commission.

Contact lens fitting means the process that begins after an initial eye examination for contact lenses and ends when a successful fit has been achieved or, in the case of a renewal prescription, ends when the prescriber determines that no change in the existing prescription is required, and such term may include:

(a) an examination to determine lens specifications;

(b) except in the case of a renewal of a contact lens prescription, an initial evaluation of the fit of the contact lens on the eye; and

(c) medically necessary follow-up examinations.

This definition is taken almost verbatim from the Act.

Contact lens prescription means a prescription, issued in accordance with State and Federal law, that contains sufficient information for the complete and accurate filling of a prescription for contact lenses, including the following:

(a) name of the patient;

(b) date of examination;

(c) issue date and expiration date of prescription;

(d) name, postal address, telephone number, and facsimile telephone number of prescriber;

(e) power, material or manufacturer or both of the prescribed contact lens;

(f) base curve or appropriate designation of the prescribed contact lens;

(g) diameter, when appropriate, of the prescribed contact lens; and

(h) in the case of a private label contact lens, name of the manufacturer, trade name of the private label brand, and, if applicable, trade name of equivalent brand name.

This definition is taken almost verbatim from the Act.

Direct communication, as used in section 315.5, includes a completed communication through telephone, facsimile, or electronic mail. This definition sets forth the ways in which direct communication, as required in section 315.5 of the proposed Rule, may occur—by telephone, facsimile, or electronic mail. The definition further requires that the communication involve a completed communication with the intended recipient. Thus, direct communication by telephone would require reaching and speaking with the intended recipient, or leaving a voice message on the telephone answering machine of the intended recipient. Similarly, direct communication by facsimile or electronic mail would require that the intended recipient receive the facsimile or electronic mail message.

Issue date, as used in section 315.6, means the date on which the patient receives a copy of the prescription. This definition is taken directly from the Act.

Ophthalmic goods are contact lenses, eyeglasses, or any component of eyeglasses. This term is not defined in the Act, and so it has been defined based on similar language in the Eyeglass Rule.

Ophthalmic services are the measuring, fitting, and adjusting of ophthalmic goods subsequent to an eye examination. This term is not defined in the Act, and so it has been defined based on similar language in the Eyeglass Rule.

Prescriber means, with respect to contact lens prescriptions, an ophthalmologist, optometrist, or other person permitted under State law to issue prescriptions for contact lenses in compliance with any applicable requirements established by the Food

and Drug Administration. This definition is taken directly from the Act.

Private Label Contact Lenses mean contact lenses that are sold under the label of a seller where the contact lenses are identical to lenses made by the same manufacturer but sold under the labels of other sellers. This definition is derived from the Act.

Section 315.3 Availability of Contact Lens Prescriptions to Patients

The Act requires prescribers to provide patients with a copy of their contact lens prescription upon completion of a contact lens fitting. It also mandates that prescribers provide or verify contact lens prescriptions to third parties authorized to act on behalf of patients. The Act further prohibits prescribers from refusing to release or verify a prescription unless their patients purchase contact lenses from them, pay a fee in addition to or as part of a examination fee, or sign a waiver or release of liability. Section 315.3 of the proposed Rule is taken almost verbatim from the Act.

Section 315.4 Limits on Requiring Immediate Payment

The Act provides that prescribers can require patients to pay a fee for an eye examination, fitting, and evaluation before the release of a contact lens prescription only if the prescriber requires immediate payment for an examination that reveals that the patient does not need contact lenses or other ophthalmic goods. The Act treats presentation of proof of insurance coverage as a type of payment. Section 315.4 of the proposed Rule is taken directly from the Act.

Section 315.5 Prescriber Verification

(a) Prescription Requirement

The Act states that a seller cannot sell contact lenses to a customer unless the seller has obtained a copy of the patient's contact lens prescription, or verified the prescription through a direct communication with the prescriber. Section 315.5(a) of the proposed Rule incorporates these preconditions verbatim from the Act.

(b) Information for Verification

The Act sets forth with specificity the information that a seller must provide to the prescriber when seeking verification of a contact lens prescription. Under the Act, the seller must provide the prescriber with the following information through direct communication: (1) The patient's full name and address; (2) the contact lens power, manufacturer, base curve or appropriate designation, and diameter when appropriate; (3) the quantity of lenses ordered; (4) the date of the patient request; (5) the date and time of the verification request; and (6) the name of a contact person at the seller's company, including a facsimile and a telephone number. Section 315.5(b) of the proposed Rule incorporates these requirements verbatim from the Act.

(c) Verification Events

The Act sets forth three circumstances under which a seller can consider a prescription verified and proceed to sell contact lenses to its customer. Under the Act, a prescription is verified if: (1) The prescriber has confirmed the prescription is accurate by direct communication with the seller; (2) the prescriber has informed the seller that the prescription is inaccurate and provides the accurate prescription; or (3) the prescriber fails to communicate with the seller within eight (8) business hours (or a similar time period defined by the Commission) after receiving a proper verification request from the seller.

Section 315.5(c) sets forth these circumstances, generally repeating the language of the Act. This provision clarifies, however, that prescribers must use a method of direct communication (*i.e.*, telephone, facsimile, or e-mail) in conveying their response to the seller's verification request. The method of direct communication used by the prescriber to respond need not be the same method of direct communication that the seller used to send a verification request. For example, an eye care practitioner may respond by telephone to a seller's fax seeking verification. The proposed Rule also does not include any time period for responding to a verification request other than the eight business hours mentioned in the Act.

(d) Invalid Prescription

The Act articulates the obligations of the parties if a seller submits a prescription for verification that the prescriber determines is invalid. The Act mandates that the prescriber must specify for the seller the basis for concluding that any prescription is invalid or inaccurate, and, if the prescription is inaccurate, the prescriber must provide the correct information to the seller. The Act precludes a seller from filling a contact lens prescription that the prescriber has reported is inaccurate, expired, or otherwise invalid, except that a seller may fill an inaccurate prescription that the prescriber has corrected. Section 315.5(d) of the proposed Rule follows the procedures set forth in the Act for addressing invalid prescriptions.

(e) No Alteration of Prescription

The Act prohibits a seller from altering a contact lens prescription of its customer. The purpose of this requirement apparently is to make certain that consumers receive the contact lenses specified in their prescription. The Act, however, contains an exception to address so-called ''private label'' lenses. Some manufacturers make identical contact lenses that are sold under multiple labels, including the private labels of particular providers. Prescribers may be able to restrict consumer choice by writing prescriptions that are limited to specified private label contact lenses, even though these lenses are identical to other lenses made by the same manufacturer and sold by other sellers. To address such a restriction, the Act allows sellers to fill a prescription with identical lenses manufactured by the same company even though the lenses are being sold under a different label than that specified on the prescription. Section 315.5(e) follows the Act in barring sellers from altering prescriptions and in allowing them to substitute identical contact lenses for a private label that a prescriber has specified on a prescription.

(f) Recordkeeping Requirement

The Act requires sellers to maintain records of all direct communications relating to prescription verification. Section 315.5(f) proposes to require that sellers maintain records of such communications, as well as any prescriptions they receive from patients or prescribers, for a period of at least three years, and to have those records available for inspection by the Federal Trade Commission. The purpose of these recordkeeping requirements is to allow the Commission to investigate whether there has been a rule violation and to seek civil penalties for any such violations. Given that the statute of limitations for obtaining civil penalties for rule violations under the FTC Act is three years,[10] a three-year document retention requirement would assist the Commission in investigating and challenging rule violations. Nevertheless, the FTC is particularly interested in receiving comments describing and documenting the costs and benefits of maintaining such records for three years.

Section 315.5(f)(1) requires that sellers keep copies of prescriptions or fax copies of prescriptions they receive directly from a patient or a prescriber. The purpose of this requirement is to

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

document that it was permissible for the seller to sell contact lenses to the customer under section 7603(a)(1) of the Act.

Section 315.5(f)(2), consistent with section 7603(b) of the Act, also mandates that sellers must maintain documentation of verification requests. The documents that the proposed rules would require sellers to preserve vary based on the means of direct communication the seller employed to seek verification. If the seller communicates through facsimile or e-mail, it must maintain a copy of the verification request and a confirmation of the completed communication of that request, including the date and time the communication was completed. On the other hand, if the seller communicates through telephone, the seller must maintain a telephone log: (1) Describing the information that the seller provided to the prescriber (*e.g.*, noting that the seller read the required prescription information to the prescriber); (2) recording the date and time the telephone call was completed; and (3) indicating how the call was completed (*e.g.*, by speaking with someone directly (and if so whom) or by leaving a message). In addition, for communications by telephone, the seller must retain copies of its telephone bills.

Section 315.5(f)(3) further mandates that the seller must maintain copies of all prescription verification responses from prescribers. Again, the specific documents to be maintained differ based on the method of direct communication that the prescriber used to contact the seller. If the response to a verification request occurs via facsimile or e-mail, the seller must preserve a copy of the communication and a record of the time and date it was received. If the response to a verification request is communicated via telephone, then the seller must maintain a telephone log describing the information communicated and the date and time that it was received.

Section 315.6 Expiration of Contact Lens Prescriptions

The Act provides that if the expiration date for a contact lens prescription under state law is one year or more after its issue date, then the prescription shall expire on the date specified by State law. The Act also states that if the expiration date for a contact lens prescription under State law is less than one year after its issue date, or the State law does not specify an expiration date, then the prescription shall expire not less than one year after its issue date. Notwithstanding these expiration standards, the Act further provides that a prescriber may specify a different expiration date based on his or her medical judgment with respect to the ocular health of the patient. The purpose of establishing a minimum expiration date as a matter of Federal law is to prevent prescribers from selecting a short expiration date for a prescription that unduly limits the ability of consumers to purchase contact lenses from other sellers, unless legitimate medical reasons justify setting such an expiration date.

Section 315.6(a) of the proposed Rule closely tracks the expiration date requirements set forth in the Act, as described above. Section 315.6(b) sets forth the procedures that prescribers must follow if they determine that legitimate medical reasons warrant an expiration date of less than one year. Specifically, prescribers must document these medical reasons in the patient's medical record with sufficient detail to allow a qualified medical professional to determine the reasonableness of the shorter expiration date. As with the documents that sellers must maintain pursuant to section 315.5(f) of the proposed Rule, section 315.6(b) requires that prescribers maintain these medical records for at least three years and that they must be available for inspection by the Federal Trade Commission.

Section 315.7 Content of Advertisements and Other Representations

The Act provides that any person that engages in the manufacture, processing, assembly, sale, offering for sale, or distribution of contact lenses may not represent, by advertisement, sales presentation, or otherwise, that contact lenses may be obtained without a prescription. Section 315.7 incorporates this provision verbatim from the Act.

Section 315.8 Prohibition of Certain Waivers

The Act provides that a prescriber may not 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 prescriber for the accuracy of the eye examination. The Act further provides that this provision does not impose liability on a prescriber for the ophthalmic goods and services dispensed by another seller pursuant to the prescriber's correctly verified prescription. Section 315.8 incorporates these provisions verbatim from the Act.

Section 315.9 Enforcement

The Act provides that any violation of the Act or rules implementing the Act shall be treated as a violation of a rule under section 18 of the Federal Trade Commission Act, 15 U.S.C. 57a, regarding unfair or deceptive acts or practices. The Act further provides that the Commission will enforce its implementing rules in the same manner, by the same means, and with the same jurisdiction, powers, and duties as are available to it pursuant to the Federal Trade Commission Act, 15 U.S.C. 41 *et seq*. Section 315.9 expressly incorporates these provisions from the Act.

Section 315.10 Severability

Section 315.10 states that the provisions of the Contact Lens Rule are separate and severable from one another. If any provision is stayed or determined to be invalid, it thus is the Commission's intention that the remaining provisions will continue in effect.

III. Overview of the Proposed Clerical Amendments to the Ophthalmic Practice Rules (16 CFR Part 456)

The Commission enforces the Ophthalmic Practice Rules, 16 CFR part 456, which primarily address acts and practices related to eyeglasses, not contact lenses. To clarify the relationship between the Ophthalmic Practice Rules and the proposed Contact Lens Rule, the Commission hereby proposes two clerical amendments to the Ophthalmic Practice Rules. The first amendment is to change the title of the Ophthalmic Practices Rules to ''Ophthalmic Practice Rules (Eyeglass Rule).'' The second amendment is to add to the Ophthalmic Practice Rules a cross-reference to the Contact Lens Rule. A similar cross-reference to the Ophthalmic Practice Rules is included in section 315.1 of the proposed Contact Lens Rule. The Commission believes modifying the title of the Ophthalmic Practices Rules to include a reference to eyeglasses and including cross-references in both set of rules will help direct businesses and consumers to applicable regulatory provisions.[11]

IV. Invitation to Comment

Comments from members of the public are invited, and may be filed with the Commission in either paper or electronic form. The Commission will give consideration to any written comments concerning the proposed

[11] Because the proposed amendments are clerical, not substantive, in nature, they are exempt from the rulemaking requirements that would apply to any substantive amendments to the Ophthalmic Practice Rules. *See* 18 U.S.C. 57(d)(1)(B). Nonetheless, in an exercise of its discretion, the Commission seeks comment on the proposed amendments in conjunction with the comments it seeks on the proposed Contact Lens Rule.

Contact Lens Rule and the clerical amendments to the Ophthalmic Practice Rules submitted on or before April 5, 2004.

A public comment filed in paper form should be mailed or delivered to the following address: Federal Trade Commission/Office of the Secretary, Room 159–H, (Annex A) 600 Pennsylvania Avenue, NW., Washington, DC 20580. If the comment contains any material for which confidential treatment is requested, it must be filed in paper (rather than electronic) form, and the first page of the document must be clearly labeled ''Confidential.'' [12]

A public comment that does not contain any material for which confidential treatment is requested may instead be filed in electronic form (in ASCII format, WordPerfect, or Microsoft Word), as part of or as an attachment to an e-mail message sent to the following e-mail box: *contactlensrule@ftc.gov*.

Regardless of the form in which they are filed, all timely comments will be considered by the Commission, and will be available (with confidential material redacted) for public inspection and copying on the Commission Web site at *http://www.ftc.gov* and at its principal office. As a matter of discretion, the Commission makes every effort to remove home contact information for individuals from the public comments it receives, before placing those comments on the FTC Web site.

V. Communications by Outside Parties to Commissioners or Their Advisors

Written communications and summaries or transcripts of oral communications respecting the merits of this proceeding from any outside party to any Commissioner or Commissioner's advisor will be placed on the public record. *See* 16 CFR 1.26(b)(5).

VI. Paperwork Reduction Act

The Commission has submitted this proposed Rule and a Supporting Statement for Information Collection Provisions to the Office of Management and Budget (''OMB'') for review under the Paperwork Reduction Act of 1995 (''PRA''), 44 U.S.C. 3501–3517. As required by the Fairness to Contact Lens Consumers Act, the proposed Rule imposes certain disclosure and recordkeeping requirements on contact lens prescribers and sellers. Specifically, the Rule requires prescribers to provide a copy of a patient's contact lens prescription to the patient or an authorized third party upon completion of a contact lens fitting, and further requires prescribers to document in their patients' records the medical reasons for setting a contact lens prescription expiration date of less than one year.[13] In addition, the Rule requires contact lens sellers to maintain records for three years of all direct communications involved in obtaining verification of a contact lens prescription, as well as prescriptions, or copies thereof, which they receive directly from customers or prescribers.[14]

The Commission staff estimates the paperwork burden of the Act and proposed Rule, based on its knowledge of the eye care industry. The staff believes there will be some burden on individual prescribers to provide contact lens prescriptions, although it involves merely writing a few pieces of information onto a slip of paper and handing it to the patient, or perhaps mailing or faxing it to a third party. The burden of documenting the medical reasons for setting a prescription expiration date shorter than one year will be minimal, because such expiration dates presumably will be set in a relatively limited number of cases, and because such records are likely kept in the ordinary course of business in any event. In addition, there will be some recordkeeping burden on contact lens sellers—including retaining prescriptions or records of ''direct communications''—pertaining to each sale of contact lenses to consumers who received their original prescription from a third party prescriber.

Overall, the Commission staff has estimated that the average annual burden during the three-year period for which OMB clearance is sought will be 900,000 burden hours. The estimated annual labor cost associated with these paperwork burdens is $28.2 million. Specifically, the staff estimates that prescribers will spend an average of one (1) minute providing each prescription to a patient or authorized third party. Based on its knowledge of the industry, the staff estimates that there are 36 million contact lens wearers in the United States who visit their eye care practitioner annually, and thus prescribers will spend 600,000 hours complying with the disclosure requirement [(36 million × 1 minute) / 60 minutes = 600,000].[15] At an average wage for prescribers of $42.00 per hour,[16] complying with this requirement imposes an estimated $25.2 million labor cost burden on prescribers [$42.00 × 600,000 hours = $25.2 million].[17] In addition, the staff estimates that contact lens sellers will spend an average of five (5) minutes per sale of contact lenses complying with the recordkeeping requirements. Based on its knowledge of the industry, the staff estimates that approximately 10% of contact lens sales (*i.e.*, sales by mail order and Internet-based sellers) will be subject to the recordkeeping requirements, 3.6 million consumers' prescriptions or verifications will need to be retained, for a total of 300,000 hours spent on recordkeeping [(3.6 million × 5 minutes) / 60 minutes = 300,000 hours]. At an average wage for clerical personnel of $10.00 per hour, complying with this requirement imposes an estimated $3 million labor cost burden on contact lens sellers [$10.00 × 300,000 hours = $3 million].[18]

The Commission invites comments that will enable it to: (1) Evaluate whether the proposed collections of information are necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) evaluate the accuracy of the Commission's estimate of the burden of the proposed collections of information, including the validity of the methodology and assumptions used; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collections of information on those who must comply, including through the use of appropriate automated, electronic, mechanical, or other technological techniques or other forms of information technology.

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[12] Commission Rule 4.2(d), 16 CFR 4.2(d). The comment must also be accompanied by an explicit request for confidential treatment, including the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. The request will be granted or denied by the Commission's General Counsel, consistent with applicable law and the public interest. *See* Commission Rule 4.9(c), 16 CFR 4.9(c).

[13] *See* proposed Rule sections 315.3(a), 315.6(b)(1); *see also* 15 U.S.C. 7601(a), 7604(b)(1).

[14] *See* proposed Rule section 315.5(f); *see* also 15 U.S.C. 7603(b).

[15] The staff estimates that prescribers will not spend any additional time complying with the recordkeeping requirement that they record the medical reasons for setting a prescription expiration date shorter than one year. This is because instances of shorter expiration dates will occur relatively infrequently and the required medical information is likely to be recorded in the ordinary course of business in any event.

[16] The Bureau of Labor Statistics reports an average wage for salaried optometrists of $42.00 per hour.

[17] This estimate overstates the actual burden, in fact, because prescribers in more than two-thirds of the States already provide prescriptions to at least some of their patients as required by State Law.

[18] Again, this estimate overstates that actual burden, because some mail order and Internet-based contact lens sellers already maintain records relating to contact lens prescriptions and verification.

VII. Regulatory Flexibility Act

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 Analysis (''FRFA'') with the final rule, if any, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. *See* 5 U.S.C. 603–605.

The FTC does not expect that the proposed Contact Lens Rule will have a significant economic impact on a substantial number of small entities. The Fairness to Contact Lens Consumers Act [19] expressly mandates most, if not all, of the proposed Rule's requirements, and thus accounts for most, if not all, of the economic impact of the proposed Rule. In any event, the burdens most likely to be imposed on small entities (which are likely to be contact lens prescribers)—such as providing contact lens prescriptions to patients or their agents, recording the medical reasons for setting prescription expiration dates of less than one year, and verifying prescription information—are likely to be relatively small. The more significant burdens imposed by the Rule likely will fall primarily on larger sellers of contact lenses, which are more likely to be seeking verification of prescriptions and thus triggering the Act's more significant recordkeeping requirements.

This document serves as notice to the Small Business Administration of the agency's certification of no effect. Nonetheless, the Commission has determined that it is appropriate to publish an IRFA in order to inquire into the impact of the proposed Rule on small entities. Therefore, the Commission has prepared the following analysis.

A. Description of the Reasons That Action by the Agency Is Being Considered

The Fairness to Contact Lens Consumers Act directs the Commission to prescribe rules implementing the Act not later than 180 days after the Act takes effect on February 4, 2004.[20] Accordingly, the Commission has prepared the proposed Contact Lens Rule announced in this document.

B. Succinct Statement of the Objectives of, and Legal Basis for, the Proposed Rules

As set forth above, the objective of the proposed Contact Lens Rule is to implement the requirements of the Fairness to Contact Lens Consumers Act. The legal basis for the proposed Rule is the Act itself, 15 U.S.C. 7601–7610.

C. Description of and, Where Feasible, Estimate of the Number of Small Entities to Which the Proposed Rule Will Apply

In general, the proposed Rule applies to both ''prescribers'' and ''sellers'' of contact lenses. The FTC staff believes that many prescribers will fall into the category of small entities (*e.g.*, Offices of Optometrists less than $6 million in size), but that, for the most part, sellers subject to the Rule's recordkeeping requirements likely will be larger businesses (*e.g.*, Mail Order Houses or Electronic Shopping entities greater than $21 million in size).[21] Determining a precise estimate of the number of small entities covered by the Rule's disclosure and recordkeeping requirements is not readily feasible. The Commission invites comment and information on this issue.

D. Projected Reporting, Recordkeeping and Other Compliance Requirements, Including an Estimate of the Classes of Small Entities That Will Be Subject to the Requirement and the Type of Professional Skills Necessary for Preparation of the Report or Record

As mandated by the Act, the proposed Rule imposes disclosure and recordkeeping requirements, within the meaning of the Paperwork Reduction Act, on contact lens prescribers and sellers. With respect to disclosure, the Rule requires prescribers to provide patients with a copy of their contact lens prescription upon completion of a contact lens fitting, and to provide such prescriptions to third parties authorized to act on behalf of patients.[22]

The Rule also implements several recordkeeping requirements. First, in cases in which a prescriber sets a contact lens prescription expiration date shorter than one year, the prescriber must document in the patient's record the medical reasons justifying the shorter expiration date.[23] Section 315.5(f) of the proposed Rule requires that such records be kept for three (3) years. Second, the Act requires sellers to maintain records of all direct communications relating to prescription verification.[24] Accordingly, section 315.5(f) of the proposed Rule requires that sellers maintain records of such communications, as well as prescriptions they receive directly from the patient or prescriber, for a period of at least three years. The specific records a seller must retain vary depending on the manner of communication. If the communication occurs through facsimile or email, the seller must retain a copy of the verification request, a confirmation of the completed communication of that request (including the date and time the communication was completed), and any response from the provider. If the communication occurs through telephone, the required record consists of a telephone log describing the information provided, the date and time of the telephone call, and how the call was completed (*e.g.*, by speaking with someone directly or leaving a message). For telephone communications the seller also must retain its telephone bill. The proposed Rule requires that the records be available for inspection by the Commission, but does not otherwise require production of the records.

The Commission is seeking clearance from the Office of Management and Budget (''OMB'') for these requirements and the Commission's Supporting Statement submitted as part of that process will be made available on the public record of this rulemaking. As set forth in section VI above, the Commission staff has estimated that the proposed Rule's disclosure and recordkeeping requirements referenced above will require an average annual burden of 600,000 hours on prescribers, for a total annual labor cost of $25.2 million, and an average annual burden on sellers of 300,000 hours on sellers, for a total annual labor cost of $3 million.

E. Other Duplicative, Overlapping, or Conflicting Federal Rules

The FTC believes there are no other Federal statutes, rules, or policies that would conflict with the proposed Rule. In fact, the proposed Rule reinforces the existing Federal requirement that contact lenses be sold only pursuant to a prescription,[25] and complements the Commission's existing Ophthalmic Practices Rule's requirement that prescribers provide patients with a copy of their eyeglass prescription upon the completion of an eye examination.[26]

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[19] 15 U.S.C. 7601–7610.

[20] 15 U.S.C. 7607.

[21] *See* 12 CFR 121.201 (Small Business Administration's Table of Small Business Size Standards).

[22] 15 U.S.C. 7601.

[23] 15 U.S.C. 7604(b).

[24] 15 U.S.C. 7603(b).

[25] Labeling regulations of the Food and Drug Administration effectively require that contact lenses are sold only pursuant to a prescription. Certain devices, such as contact lenses, when sold without a prescription and without adequate directions for use on the label, are ''misbranded'' in violation of the Food, Drug & Cosmetics Act. *See* 21 U.S.C. 352(f); 21 CFR 801.109(a)(2).

[26] *See* 16 CFR 456.2(a).

F. Description of Any Significant Alternatives to the Proposed Rule That Would Accomplish the Stated Objectives of Applicable Statutes and That Minimize Any Significant Economic Impact of the Proposed Rule on Small Entities, Including Alternatives Considered, Such as: (1) Establishment of Differing Compliance or Reporting Requirements or Timetables That Take Into Account the Resources Available to Small Entities; (2) Clarification, Consolidation, or Simplification of Compliance and Reporting Requirements Under the Rule for Such Small Entities; (4) Any Exemption From Coverage of the Rule, or Any Part Thereof, for Such Small Entities

The proposed Rule's disclosure and recordkeeping requirements are designed to impose the minimum burden on all affected members of the industry, regardless of size. The Act itself does not allow the Commission any latitude to treat small businesses differently, such as by exempting a particular category of firm or setting forth a lesser standard of compliance for any category of firm. However, the burdens imposed by the Act and proposed Rule on small businesses are likely to be relatively limited. The small businesses affected by the Rule are likely to consist primarily of contact lens prescribers in solo or small practices. Their burdens under the Rule primarily would entail providing contact lens prescriptions to patients or their agents, documenting in exceptional cases the medical reasons for setting a contact lens prescription date of less than one year, and verifying prescriptions for some of their patients who seek to purchase their contact lenses from another seller. Thus, the Commission does not believe that the proposed Rule will impose a significant economic impact on a substantial number of small businesses.

Nonetheless, the Commission specifically requests comment on the question whether the proposed Rule imposes a significant impact upon a substantial number of small entities, and what modifications to the Rule the Commission could make to minimize the burden on small entities. Moreover, the Commission requests comment on the general question whether new technology or changes in technology can be used to reduce the burdens mandated by the Act.

Questions for Comment To Assist Regulatory Flexibility Analysis

1. Please provide information or comment on the number and type of small entities affected by the proposed Rule. Include in your comments the number of small entities that will be required to comply with the Rule's disclosure and recordkeeping requirements.

2. Please provide comment on any or all of the provisions in the proposed Rule with regard to (a) the impact of the provision(s) (including benefits and costs), if any, and (b) what alternatives, if any, the Commission should consider, as well as the costs and benefits of those alternatives, paying specific attention to the effect of the proposed Rule on small entities in light of the above analysis. In particular, please provide the above information with regard to the disclosure and recordkeeping provisions of the proposed Rule set forth in sections 315.3(a), 315.5(f), and 315.6(b), and describe any ways in which the proposed Rule could be modified to reduce any costs or burdens for small entities consistent with the Act's mandated requirements. Costs to ''implement and comply'' with the proposed Rule include expenditures of time and money for: any employee training; attorney, computer programmer or other professional time; preparing relevant materials (*i.e.*, prescriptions for release), and recordkeeping.

3. Please describe ways in which the Rule could be modified to reduce any costs or burdens on small entities consistent with the Act's mandated requirements, including whether and how technological developments could reduce the costs of implementing and complying with the proposed Rule for small entities.

4. Please provide any information quantifying the economic benefits of the proposed Rule on the entities covered by the Act, including small entities.

5. Please identify any relevant Federal, State, or local rules that may duplicate, overlap or conflict with the proposed Rule. In addition, please identify any industry rules or policies that require covered entities to engage in business practices that would already comply with the requirements of the proposed Rule.

VIII. Effective Date

The Act takes effect on February 4, 2004,[27] and thus prescribers and sellers of contact lenses, and other parties covered by the Act, have a legal obligation to comply with the Act as of that date. The Act directs the Commission to prescribe rules that will become effective no later than 180 days after the effective date of the Act.[28] The FTC intends to issue final rules with an effective date within the time specified in the Act. The Commission will announce a specific effective date for the Contact Lens Rule when it issues its final rule.

IX. Questions on the Proposed Contact Lens Rule and the Proposed Clerical Amendments to the Ophthalmic Practice Rules

The Commission is seeking comment on various aspects of the proposed Contact Lens Rule, and is particularly interested in receiving comment on the questions that follow. These questions are designed to assist the public and should not be construed as a limitation on the issues on which public comment may be submitted. Responses to these questions should cite the numbers and subsection of the questions being answered. For all comments submitted, please submit any relevant data, statistics, or any other evidence, upon which those comments are based.

General Questions

1. Please provide comment on any or all of the provisions in the proposed Contact Lens Rule and the proposed clerical amendments to the Ophthalmic Practice Rules. For each provision commented on please describe (a) the impact of the provision(s) (including benefits and costs), if any, and (b) what alternatives, if any, the Commission should consider, as well as the costs and benefits of those alternatives.

2. Please provide comment on the effect of the proposed Contact Lens Rule on the costs, profitability, and competitiveness of, and employment in, small entities.

Questions Pertaining to the Proposed Contact Lens Rule

Definitions

3. Section 315.2 defines ''business hour.'' (a) Is this definition sufficiently clear?

(b) What is the impact, including costs and benefits, of defining the term in this way? (c) Should the definition include provisions addressing (i) prescriber vacation days, (ii) State or local holidays, (iii) weekend days, or (iv) other exceptions to normal business hours?

4. Section 315.2 defines ''contact lens fitting.'' (a) Is this definition sufficiently clear? (b) What is the impact, including costs and benefits, of defining the term in this way? (c) Should the term ''medically necessary follow-up

[27] The Act becomes effective 60 days after the date of its enactment, which was December 6, 2003. *See* Pub. L. 108–164, section 12 (set out as note under 15 U.S.C. 7601).

[28] 15 U.S.C. 7607.

examinations'' be defined, and, if so, how?

5. Section 315.2 defines ''contact lens prescription.'' (a) Is this definition sufficiently clear? (b) What is the impact, including costs and benefits, of defining the term in this way? (c) Should the definition include the prescriber's e-mail address, if any? (d) Should the definition include anything else?

6. Should the Commission define ''contact lenses'' for purposes of the Act, and, if so, should such definition specifically exclude non-corrective or ''cosmetic'' contact lenses, because consumers do not need a prescription to purchase them?

7. Section 315.2 defines ''direct communication.'' (a) Is this definition sufficiently clear? (b) What is the impact, including costs and benefits, of defining the term in this way? (c) Is it appropriate to include messages left on telephone answering machines in this definition? (d) Should the definition expressly require, for communication by facsimile or e-mail, the receipt of a confirmation that the communication was successful? (e) Should the definition include any other means of direct communication?

8. Section 315.2 defines ''issue date.'' (a) Is this definition sufficiently clear? (b) Is this term currently defined under State laws relating to contact lens prescriptions? (c) What is the impact, including costs and benefits, of defining the term in this way?

9. Section 315.2 defines ''ophthalmic goods.'' (a) Is this definition sufficiently clear? (b) Is there any reason that ophthalmic goods should be defined differently for purposes of the proposed Contact Lens Rule and the Ophthalmic Practice Rules? (c) What is the impact, including costs and benefits, of defining the term in this way?

10. Section 315.2 defines ''ophthalmic services.'' (a) Is this definition sufficiently clear? (b) Is there any reason that ophthalmic services should be defined differently for purposes of the proposed Contact Lens Rule and the Ophthalmic Practice Rules? (c) What is the impact, including costs and benefits, of defining the term in this way?

11. Section 315.2 defines ''prescriber.'' (a) Is this definition sufficiently clear? (b) What is the impact, including costs and benefits, of defining the term in this way?

12. Section 315.2 defines ''private label contact lenses.'' (a) Is this definition sufficiently clear? (b) What is the impact, including costs and benefits, of defining the term in this way?

Availability of Contact Lens Prescriptions to Patients

13. Section 315.3(a) requires prescribers to release and verify contact lens prescriptions to their patients and to any person designated to act on behalf of the patient. (a) Is this provision sufficiently clear? (b) Is it clear the means by which a prescriber shall provide or verify a contact lens prescription as directed by a third party authorized to act on behalf of the patient?

14. Section 315.3(b) prohibits prescribers from imposing certain requirements or conditions on patients prior to releasing or verifying contact lens prescriptions, including charging them any fee in addition to the fee for an eye examination, fitting, and evaluation to receive a prescription or to have a prescription verified. (a) Do prescribers itemize charges and fees in a manner that distinguishes the amount the patient is paying for an eye examination, fitting, and evaluation from the amount he or she is paying for other goods and services? (b) Are there additional requirements or conditions that should be prohibited to facilitate the release and verification of contact lens prescriptions? (c) What would be the impact, including costs and benefits, of such additional prohibitions?

Limits on Requiring Immediate Payment

15. Section 315.4 limits the circumstances under which a prescriber may require immediate payment for fees for an eye examination, fitting, and evaluation prior to releasing a contact lens prescription. Is this provision sufficiently clear?

Prescriber Verification

16. Section 315.5(a) sets forth the circumstances under which contact lens sellers may sell contact lenses to a patient. (a) Is this provision sufficiently clear, and, if not, what should be clarified? (b) Should the Commission specify, for purposes of paragraph (a)(1), that either the original or a copy of a prescription will suffice? (c) Are there additional requirements the Commission should consider imposing, and what would be the impact, including costs and benefits, of such additional requirements?

17. Section 315.5(b) sets forth the information a contact lens seller must provide to a prescriber when the seller seeks verification of a contact lens prescription. (a) Is this provision sufficiently clear? (b) What is the impact, including costs and benefits, of this provision? (c) Is there any additional information a prescriber needs in order to verify a contact lens prescription? (d) If prescribers receive the name of a contact person at the seller, as well as his or her telephone number and fax number, is this sufficient to enable a prescriber to respond to a verification request within eight (8) business hours as defined in section 315.5(c)?

18. Section 315.5(c) defines the circumstances under which a contact lens prescription is deemed verified. (a) Is this provision sufficiently clear? (b) What is the impact, including costs and benefits, of this provision? (c) Is there a different time period that is similar to eight business hours, as set forth in section 315.5(c)(3), that would give prescribers an adequate period of time during normal office hours to act upon a prescription verification request and still allow sellers to fill customer orders expeditiously? (d) What would be the impact, including costs and benefits, of such other time period? (e) Does the Health Insurance Portability and Accountability Act of 1996 (''HIPAA'') limit or otherwise affect prescribers' ability to respond to a verification request pursuant to section 315.5(c) and/or section 315.5(d)?

19. Section 315.5(d) prohibits a contact lens seller from filling a prescription if the prescriber provides timely notice to the seller that the prescription is inaccurate, expired, or otherwise invalid, unless the prescriber has corrected the inaccuracy. (a) Is this provision sufficiently clear? (b) Should the Commission specifically define inaccurate, invalid, and expired prescriptions, and, if so, what should those definitions include? (c) What is the impact, including the costs and benefits, of this provision?

20. Section 315.5(e) prohibits sellers from altering contact lens prescriptions, but allows them to substitute identical contact lenses from the same manufacturer for private label lenses specified on a prescription. (a) Is this provision sufficiently clear? (b) What is the impact, including costs and benefits, of this provision?

21. Section 315.5(f) requires contact lens sellers to maintain for three (3) years records of prescriptions received, direct communications with prescribers to verify prescriptions, and responses from prescribers to these requests for verification. (a) Is this provision sufficiently clear? (b) What is the impact, including costs and benefits, of this provision—particularly with respect to the types of documents and the length of time they must be retained? (c) Are there additional items the Commission should require be maintained? (d) How can the

Commission minimize the burden on sellers imposed by the recordkeeping requirement? (e) Are there technological means available to provide confirmation to the sender that an email has been received by the intended recipient?

Expiration of Contact Lens Prescriptions

22. Section 315.6(a) establishes a minimum contact lens prescription expiration date of one year, subject to an exception based on the medical judgment of a prescriber. (a) Is this provision sufficiently clear? (b) What is the impact, including the costs and benefits, of this provision?

23. Section 315.6(b) sets forth special rules for contact lens prescriptions that expire in less than one year, including a requirement that prescribers document the specific reasons for the medical judgment on which the shorter expiration date is based. (a) Is this provision sufficiently clear? (b) What is the impact, including the costs and benefits, of this provision? (c) In what circumstances would there be legitimate medical reasons for setting a contact lens prescription expiration date of less than one year? (d) How can the Commission minimize the burden on prescribers imposed by the documentation requirement and the three-year time period for retention? (e) For how long do prescribers currently retain medical records for their contact lens patients?

Content of Advertisements and Other Representations

24. Section 315.7 prohibits the representation that contact lenses may be obtained without a prescription. (a) Is this provision sufficiently clear? (b) What is the impact, including the costs and benefits, of this provision? (c) Should the Commission clarify that this provision applies only to contact lenses for which a prescription is required, *i.e.*, that it does not apply to non-corrective or ''cosmetic'' contact lenses?

Prohibition of Certain Waivers

25. Section 315.8 prohibits prescribers from waiving liability or responsibility for the accuracy of the eye examination. (a) Is this provision sufficiently clear? (b) What is the impact, including the costs and benefits, of this provision?

Enforcement

26. Section 315.9 explains how the Commission will treat violations of the Contact Lens Rule and defines the scope of the agency's enforcement power and jurisdiction. (a) Is this provision sufficiently clear? (b) What is the impact, including the costs and benefits, of this provision?

Questions on the Proposed Clerical Amendments to the Ophthalmic Practice Rules

27. The Commission proposes amending the title of 16 CFR Part 456 to read: Ophthalmic Practice Rules (Eyeglass Rule). What is the impact, if any, of such an amendment and would it effect any substantive change to the Rules?

28. The Commission proposed adding a new paragraph 456.5 to the Ophthalmic Practices Rules to provide a cross-reference to the Contact Lens Rule. What is the impact, if any, of such an amendment and would it effect any substantive change to the Rules?

X. Proposed Contact Lens Rule and Clerical Amendments to the Ophthalmic Practice Rules (16 CFR Part 456)

List of Subjects in 16 CFR Parts 315 and 456

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

Accordingly, for the reasons stated in the preamble, the Federal Trade Commission proposes to amend 16 CFR chapter I as follows:

1. Add a new part 315 to subchapter C to read as follows:

PART 315—CONTACT LENS RULE

Sec.

Authority: Pub. L. 108–164, secs. 1–12; 15 U.S.C. 7601–7610.

§ 315.1 Scope of regulations in this part.

This part, which shall be called the ''Contact Lens Rule,'' implements the Fairness to Contact Lens Consumers Act, codified at 15 U.S.C. 7601–7610, which requires that rules be issued to address the release and verification of contact lens prescriptions. This part specifically governs contact lens prescriptions and related issues. Part 456 of Title 16 governs the availability of eyeglass prescriptions and related issues. 16 CFR part 456 (the Ophthalmic Practice Rules (Eyeglass Rule)).

§ 315.2 Definitions.

Business hour means an hour between 9 a.m. and 5 p.m., during a weekday (Monday through Friday), excluding Federal holidays. For purposes of § 315.5(d)(3), ''eight (8) business hours'' shall be calculated from the first business hour that occurs after the seller provides the prescription verification request to the prescriber, and shall conclude after eight (8) business hours have elapsed. For verification requests received by a prescriber during non-business hours, the calculation of ''eight (8) business hours'' shall begin at 9 a.m. on the next weekday that is not a Federal holiday.

Commission means the Federal Trade Commission.

Contact lens fitting means the process that begins after an initial eye examination for contact lenses and ends when a successful fit has been achieved or, in the case of a renewal prescription, ends when the prescriber determines that no change in the existing prescription is required, and such term may include:

(1) An examination to determine lens specifications;

(2) Except in the case of a renewal of a contact lens prescription, an initial evaluation of the fit of the contact lens on the eye; and

(3) Medically necessary follow-up examinations.

Contact lens prescription means a prescription, issued in accordance with State and Federal law, that contains sufficient information for the complete and accurate filling of a prescription for contact lenses, including the following:

(1) The name of the patient;

(2) The date of examination;

(3) The issue date and expiration date of prescription;

(4) The name, postal address, telephone number, and facsimile telephone number of prescriber;

(5) The power, material or manufacturer or both of the prescribed contact lens;

(6) The base curve or appropriate designation of the prescribed contact lens;

(7) The diameter, when appropriate, of the prescribed contact lens; and

(8) In the case of a private label contact lens, the name of the manufacturer, trade name of the private label brand, and, if applicable, trade name of equivalent brand name.

Direct communication, as used in § 315.5, means completed communication by telephone, facsimile, or electronic mail.

Issue date, as used in § 315.6, means the date on which the patient receives a copy of the prescription.

Ophthalmic goods are contact lenses, eyeglasses, or any component of eyeglasses.

Ophthalmic services are the measuring, fitting, and adjusting of ophthalmic goods subsequent to an eye examination.

Prescriber means, with respect to contact lens prescriptions, an ophthalmologist, optometrist, or other person permitted under State law to issue prescriptions for contact lenses in compliance with any applicable requirements established by the Food and Drug Administration.

Private Label Contact Lenses mean contact lenses that are sold under the label of a seller where the contact lenses are identical to lenses made by the same manufacturer but sold under the labels of other sellers.

§ 315.3 Availability of Contact Lens Prescriptions to Patients

(a) *In general.* When a prescriber completes a contact lens fitting, the prescriber:

(1) Whether or not requested by the patient, shall provide to the patient a copy of the contact lens prescription; and

(2) Shall, as directed by any person designated to act on behalf of the patient, provide or verify the contact lens prescription by electronic or other means.

(b) *Limitations.* A prescriber may not:

(1) Require the purchase of contact lenses from the prescriber or from another person as a condition of providing a copy of a prescription under paragraph (a)(1) or (a)(2) of this section or as a condition of verification of a prescription under paragraph (a)(2) of this section;

(2) Require payment in addition to, or as part of, the fee for an eye examination, fitting, and evaluation as a condition of providing a copy of a prescription under paragraph (a)(1) or (a) (2) of this section or as a condition of verification of a prescription under paragraph (a)(2) of this section; or

(3) Require the patient to sign a waiver or release as a condition of releasing or verifying a prescription under paragraph (a)(1) or (a)(2) of this section.

§ 315.4 Limits on Requiring Immediate Payment

A prescriber may require payment of fees for an eye examination, fitting, and evaluation before the release of a contact lens prescription, but only if the prescriber requires immediate payment in the case of an examination that reveals no requirement for ophthalmic goods. For purposes of the preceding sentence, presentation of proof of insurance coverage for that service shall be deemed to be a payment.

§ 315.5 Prescriber Verification

(a) *Prescription requirement.* A seller may sell contact lenses only in accordance with a contact lens prescription for the patient that is:

(1) Presented to the seller by the patient or prescriber directly or by facsimile; or

(2) Verified by direct communication.

(b) *Information for verification.* When seeking verification of a contact lens prescription, a seller shall provide the prescriber with the following information through direct communication:

(1) The patient's full name and address;

(2) The contact lens power, manufacturer, base curve or appropriate designation, and diameter when appropriate;

(3) The quantity of lenses ordered;

(4) The date of patient request;

(5) The date and time of verification request; and

(6) The name of a contact person at the seller's company, including facsimile and telephone numbers.

(c) *Verification events.* A prescription is verified under paragraph (a)(2) of this section only if one of the following occurs:

(1) The prescriber confirms the prescription is accurate by direct communication with the seller;

(2) The prescriber informs the seller through direct communication that the prescription is inaccurate and provides the accurate prescription; or

(3) The prescriber fails to communicate with the seller within eight (8) business hours after receiving from the seller the information described in paragraph (b) of this section.

(d) *Invalid prescription.* If a prescriber informs a seller before the deadline under paragraph (c)(3) of this section that the contact lens prescription is inaccurate, expired, or otherwise invalid, the seller shall not fill the prescription. The prescriber shall specify the basis for the inaccuracy or invalidity of the prescription. If the prescription communicated by the seller to the prescriber is inaccurate, the prescriber shall correct it, and the prescription shall then be deemed verified under paragraph (c)(2) of this section.

(e) *No alteration of prescription.* A seller may not alter a contact lens prescription. Notwithstanding the preceding sentence, a seller may substitute for private label contact lenses specified on a prescription identical contact lenses that the same company manufactures and sells under different labels.

(f) *Recordkeeping requirement.* A seller shall maintain a record of all direct communications referred to in paragraph (a) of this section. Such record shall consist of the following:

(1) For prescriptions presented to the seller: the prescription itself, or the facsimile version thereof, that was presented to the seller by the patient or prescriber.

(2) For verification requests by the seller:

(i) If the communication occurs via facsimile or e-mail, a copy of the verification request, including the information provided to the prescriber pursuant to paragraph (b) of this section, and confirmation of the completed transmission thereof, including a record of the date and time the request was made.

(ii) If the communication occurs via telephone, a telephone log:

(A) Describing the information provided pursuant to paragraph (b) of this section;

(B) Setting forth the date and time the request was made; and

(C) Indicating how the call was completed.

(D) The seller also must retain copies of its telephone bills.

(3) For communications from the prescriber, including prescription verifications:

(i) If the communication occurs via facsimile or e-mail, a copy of the communication and a record of the time and date it was received.

(ii) If the communication occurs via telephone, a telephone log describing the information communicated and the date and time that the information was received.

(4) The records required to be maintained under this section shall be maintained for a period of not less than three years, and these records must be available for inspection by the Federal Trade Commission, its employees, and its representatives.

§ 315.6 Expiration of contact lens prescriptions.

(a) *In general.* A contact lens prescription shall expire:

(1) On the date specified by the law of the State in which the prescription was written, if that date is one year or more after the issue date of the prescription;

(2) Not less than one year after the issue date of the prescription if such State law specifies no date or specifies a date that is less than one year after the issue date of the prescription; or

(3) Notwithstanding paragraphs (a)(1) and (2) of this section, on the date specified by the prescriber, if that date is based on the medical judgment of the prescriber with respect to the ocular health of the patient.

(b) *Special rules for prescriptions of less than one year.* (1) If a prescription expires in less than one year, the specific reasons for the medical judgment referred to in paragraph (a)(3) of this section shall be documented in the patient's medical record with sufficient detail to allow for review by a qualified professional in the field.

(2) The documentation described in paragraph (b)(1) of this section shall be maintained for a period of not less than three years, and it must be available for inspection by the Federal Trade Commission, its employees, or its representatives.

(3) No prescriber shall include an expiration date on a prescription that is less than the period of time that he or she recommends for a reexamination of the patient that is medically necessary.

§ 315.7 Content of advertisements and other representations.

Any person that engages in the manufacture, processing, assembly, sale, offering for sale, or distribution of contact lenses may not represent, by advertisement, sales presentation, or otherwise, that contact lenses may be obtained without a prescription.

§ 315.8 Prohibition of certain waivers.

A prescriber may not place on a 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 prescriber for the accuracy of the eye examination. The preceding sentence does not impose liability on a prescriber for the ophthalmic goods and services dispensed by another seller pursuant to the prescriber's correctly verified prescription.

§ 315.9 Enforcement.

Any violation of this part shall be treated as a violation of a rule under section 18 of the Federal Trade Commission Act, 15 U.S.C. 57a, regarding unfair or deceptive acts or practices, and the Commission will enforce this part in the same manner, by the same means, and with the same jurisdiction, powers, and duties as are available to it pursuant to the Federal Trade Commission Act, 15 U.S.C. 41 *et seq.*

§ 315.10 Severability.

The provisions of this part are separate and severable from one another. If any provision is stayed or determined to be invalid, it is the Commission's intention that the remaining provisions shall continue in effect.

PART 456—AMENDED

2. The authority citation for part 456 continues to read as follows:

Authority: 15 U.S.C. 57a; 5 U.S.C. 552.

3. Revise the title of part 456 to read as follows:

PART 456—OPHTHALMIC PRACTICE RULES (EYEGLASS RULE)

4. Add a new § 456.5 to read as follows:

§ 456.5 Rules applicable to prescriptions for contact lenses and related issues.

Rules applicable to prescriptions for contact lenses and related issues may be found at 16 CFR part 315 (Contact Lens Rule).

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 04–2235 Filed 2–3–04; 8:45 am]

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