

## ELECTRONIC CODE OF FEDERAL REGULATIONS

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Title 16: Commercial Practices

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### PART 315—CONTACT LENS RULE

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**AUTHORITY:** Pub. L. 108-164, secs. 1-12; 117 Stat. 2024 (15 U.S.C. 7601-7610).

**SOURCE:** 69 FR 40508, July 2, 2004, unless otherwise noted.

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**§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, verification, and sale 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 (the Ophthalmic Practice Rules (Eyeglass Rule)).

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### §315.2 Definitions.

For purposes of this part, the following definitions shall apply:

*Business hour* means an hour between 9 a.m. and 5 p.m., during a weekday (Monday through Friday), excluding Federal holidays. “Business hour” also may include, at the seller’s option, a prescriber’s regular business hours on Saturdays, provided that the seller has actual knowledge of these hours. “Business hour” shall be determined based on the time zone of the prescriber.

“Eight (8) business hours” shall be calculated from the time the prescriber receives the prescription verification information from the seller, and shall conclude when 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 or, if applicable, on Saturday at the beginning of the prescriber’s actual business hours.

*Commission* means the Federal Trade Commission.

*Contact lens* means any contact lens for which State or Federal law requires a prescription.

*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* means completed communication by telephone, facsimile, or electronic mail.

*Issue date* means the date on which the patient receives a copy of the prescription at the completion of a contact lens fitting.

*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. "Other person," for purposes of this definition, includes a dispensing optician who is permitted under State law to issue prescriptions and who is authorized or permitted under State law to perform contact lens fitting services.

*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.

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### §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.

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### §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.

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### §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;
- (6) The name of a contact person at the seller's company, including facsimile and telephone numbers; and
- (7) If the seller opts to include the prescriber's regular business hours on Saturdays as "business hours" for purposes of paragraph (c)(3) of this section, a clear statement of the prescriber's regular Saturday business hours.

(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. During these eight (8) business hours, the seller shall provide a reasonable opportunity for the prescriber to communicate with the seller concerning the verification request.
- (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—verification requests.* 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 (including an email containing a digital image of the prescription), 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 log:

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

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

(C) Indicating how the call was completed, and

(D) Listing the names of the individuals who participated in the call.

(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 log describing the information communicated, the date and time that the information was received, and the names of the individuals who participated in the call.

(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.

(g) *Recordkeeping requirement—Saturday business hours.* A seller that exercises its option to include a prescriber's regular Saturday business hours in the time period for verification specified in §315.5(c)(3) shall maintain a record of the prescriber's regular Saturday business hours and the basis for the seller's actual knowledge thereof. Such records 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.

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### §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 (a)(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 the paragraph above 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, and 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.

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### **§315.7 Content of advertisements and other representations.**

Any person who 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.

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### **§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.

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### **§315.9 Enforcement.**

Any violation of this Rule 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 Rule 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.*

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### **§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.

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### **§315.11 Effect on state and local laws.**

(a) State and local laws and regulations that establish a prescription expiration date of less than one year or that restrict prescription release or require active verification are preempted.

(b) Any other State or local laws or regulations that are inconsistent with the Act or this part are preempted to the extent of the inconsistency.

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