PUBLIC LAW 108–164—DEC. 6, 2003

FAIRNESS TO CONTACT LENS CONSUMERS ACT

Public Law 108–164 108th Congress

An Act

Dec. 6, 2003 [H.R. 3140] To provide for availability of contact lens prescriptions to patients, and for other purposes.

Fairness to Contact Lens Consumers Act. 15 USC 7601 note. Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Fairness to Contact Lens Consumers Act".

15 USC 7601.

SEC. 2. 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 purchase of contact lenses from the prescriber or from another person as a condition of providing a copy of a prescription under subsection (a)(1) or (a)(2) or verification of a prescription under subsection (a)(2);
 - (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 subsection (a)(1) or (a)(2) or verification of a prescription under subsection (a)(2); or
 - (3) require the patient to sign a waiver or release as a condition of verifying or releasing a prescription.

15 USC 7602.

SEC. 3. IMMEDIATE PAYMENT OF FEES IN LIMITED CIRCUMSTANCES.

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.

15 USC 7603.

SEC. 4. 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) RECORD REQUIREMENT.—A seller shall maintain a record of all direct communications referred to in subsection (a).
- (c) Information.—When seeking verification of a contact lens prescription, a seller shall provide the prescriber with the following information:
 - (1) Patient's full name and address.
 - (2) Contact lens power, manufacturer, base curve or appropriate designation, and diameter when appropriate.

(3) Quantity of lenses ordered.

(4) Date of patient request.

(5) Date and time of verification request.

- (6) Name of contact person at seller's company, including facsimile and telephone number.
- (d) VERIFICATION EVENTS.—A prescription is verified under this Act 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 that the prescription

is inaccurate and provides the accurate prescription.

- (3) The prescriber fails to communicate with the seller within 8 business hours, or a similar time as defined by the Federal Trade Commission, after receiving from the seller the information described in subsection (c).
- (e) INVALID PRESCRIPTION.—If a prescriber informs a seller before the deadline under subsection (d)(3) 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.
- (f) No ALTERATION.—A seller may not alter a contact lens prescription. Notwithstanding the preceding sentence, if the same contact lens is manufactured by the same company and sold under multiple labels to individual providers, the seller may fill the prescription with a contact lens manufactured by that company under another label.
- (g) DIRECT COMMUNICATION.—As used in this section, the term "direct communication" includes communication by telephone, facsimile, or electronic mail.

SEC. 5. EXPIRATION OF CONTACT LENS PRESCRIPTIONS.

15 USC 7604.

- (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 a date that is less than one year after the issue date of the prescription; or
- (3) notwithstanding paragraphs (1) and (2), 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 1 YEAR.— If a prescription expires in less than 1 year, the reasons for the judgment referred to in subsection (a)(3) shall be documented in the patient's medical record. In no circumstance shall the prescription expiration date be less than the period of time recommended by the prescriber for a reexamination of the patient that is medically necessary.
- (c) DEFINITION.—As used in this section, the term "issue date" means the date on which the patient receives a copy of the prescription

15 USC 7605.

SEC. 6. 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.

15 USC 7606.

SEC. 7. PROHIBITION OF CERTAIN WAIVERS.

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 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.

15 USC 7607.

SEC. 8. RULEMAKING BY FEDERAL TRADE COMMISSION.

The Federal Trade Commission shall prescribe rules pursuant to section 18 of the Federal Trade Commission Act (15 U.S.C. 57a) to carry out this Act. Rules so prescribed shall be exempt from the requirements of the Magnuson-Moss Warranty—Federal Trade Commission Improvement Act (15 U.S.C. 2301 et seq.). Any such regulations shall be issued in accordance with section 553 of title 5, United States Code. The first rules under this section shall take effect not later than 180 days after the effective date of this Act.

Deadline.

15 USC 7608.

SEC. 9. VIOLATIONS.

(a) IN GENERAL.—Any violation of this Act or the rules required under section 8 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.

(b) ACTIONS BY THE COMMISSION.—The Federal Trade Commission shall enforce this Act in the same manner, by the same means, and with the same jurisdiction, powers, and duties as though all applicable terms and provisions of the Federal Trade Commission Act (15 U.S.C. 41 et seq.) were incorporated into and made a part of this Act.

15 USC 7609. **SEC.**

SEC. 10. STUDY AND REPORT.

(a) STUDY.—The Federal Trade Commission shall undertake a study to examine the strength of competition in the sale of prescription contact lenses. The study shall include an examination of the following issues:

(1) Incidence of exclusive relationships between prescribers or sellers and contact lens manufacturers and the impact of such relationships on competition.

- (2) Difference between online and offline sellers of contact lenses, including price, access, and availability.
- (3) Incidence, if any, of contact lens prescriptions that specify brand name or custom labeled contact lenses, the reasons for the incidence, and the effect on consumers and competition
- (4) The impact of the Federal Trade Commission eyeglasses rule (16 CFR 456 et seq.) on competition, the nature of the enforcement of the rule, and how such enforcement has impacted competition.
- (5) Any other issue that has an impact on competition in the sale of prescription contact lenses.
- (b) REPORT.—Not later than 12 months after the effective date Deadline. of this Act, the Chairman of the Federal Trade Commission shall submit to the Congress a report of the study required by subsection (a).

SEC. 11. DEFINITIONS.

15 USC 7610.

As used in this Act:

- (1) CONTACT LENS FITTING.—The term "contact lens fitting" means the process that begins after the initial eye examination 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 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 prescription, an initial evaluation of the fit of the lens on the eye;
 - (C) medically necessary follow up examinations.
- (2) PRESCRIBER.—The term "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.
- (3) CONTACT LENS PRESCRIPTION.—The term "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, 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.
 - (F) Base curve or appropriate designation.
 - (G) Diameter, when appropriate.
 - (H) In the case of a private label contact lens, name of manufacturer, trade name of private label brand, and, if applicable, trade name of equivalent brand name.

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15 USC 7601 note.

SEC. 12. EFFECTIVE DATE.

This Act shall take effect 60 days after the date of the enactment of this Act.

Approved December 6, 2003.