II

114TH CONGRESS
2D SESSION

S. 2777

To modernize the prescription verification process for contact lenses, to clarify consumer protections regarding false advertising of contact lenses, and for other purposes.

IN THE SENATE OF THE UNITED STATES

APRIL 11, 2016

Mr. CASSIDY (for himself and Mr. BOOZMAN) introduced the following bill; which was read twice and referred to the Committee on Commerce, Science, and Transportation

---

A BILL

To modernize the prescription verification process for contact lenses, to clarify consumer protections regarding false advertising of contact lenses, and for other purposes.

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 ''Contact Lens Consumer Health Protection Act of 2016''.

SEC. 2. IMPROVEMENT OF CONTACT LENS PRESCRIBER VERIFICATION PROCESS.

(a) IN GENERAL.—Section 4 of the Fairness to Contact Lens Consumers Act (15 U.S.C. 7603) is amended—

(1) in subsection (c), by adding at the end the following:

''(7) A toll-free telephone number and email address for prescribers to call or email with questions relating to a verification request, as required under subsection (i).'';

(2) in subsection (d)(3)—

(A) by striking '', or a similar time as defined by the Federal Trade Commission,'';

(B) by inserting ''(A)'' before ''The prescriber''; and

(C) by adding at the end the following:

''(B) If a prescriber communicates a question or concern about the accuracy of the prescription, or any other matter relating to the verification of the prescription, to a seller through the toll-free telephone service or dedicated email address required under subsection (i) before such 8-business-hour period has ended, the prescription shall be considered unverified until the seller obtains affirmative confirmation of the accuracy of the prescription from the prescriber.'';

(3) by redesignating subsections (e) through (g) as subsections (f) through (h), respectively;

(4) by amending subsection (f), as redesignated by paragraph (3), to read as follows:

''(f) INVALID PRESCRIPTIONS AND QUESTIONS CONCERNING ACCURACY.—

''(1) INVALID PRESCRIPTIONS.—If a prescriber informs a seller before the deadline set forth in subparagraph (A) of subsection (d)(3) that the contact lens prescription is inaccurate, expired, or otherwise invalid—

''(A) the seller shall not fill the prescription; and

''(B) the prescriber shall specify the basis for the inaccuracy or invalidity of the prescription.

''(2) QUESTIONS CONCERNING ACCURACY.—If a prescriber communicates a question or concern about the accuracy of a prescription as described in subsection (d)(3)(B) before the deadline set forth in such subsection—

''(A) the seller shall not fill the prescription; and

''(B) the prescriber shall provide the seller with an accurate prescription.

''(3) CORRECTION.—In any case, if the prescription communicated by the seller to the prescriber is inaccurate, the prescriber shall correct it.'';

(5) by adding after subsection (d) the following:

''(e) PRESCRIBER PREFERRED METHOD OF COMMUNICATION.—

''(1) IN GENERAL.—A prescriber may provide written notification to a seller requesting that all requests for verification from that seller be communicated to that prescriber by that prescriber's preferred method or methods of communication, selected from among the methods of communication offered by the seller pursuant to paragraph (2).

''(2) METHODS OFFERED.—Each seller shall offer a prescriber methods for communication for selection as the prescriber's preferred method or methods of communication under paragraph (1). Such offer—

''(A) shall include—

''(i) live telephone;

''(ii) facsimile; and

''(iii) email; and

''(B) may include such additional methods of communication as the seller considers appropriate.

''(3) REQUIREMENT.—In a case in which a prescriber, pursuant to paragraph (1), provides written notification to a seller indicating a preferred method or methods of communication as described in such paragraph, the seller may only request verification from the prescriber through the method or methods indicated.''; and

(6) by inserting after subsection (h), as redesignated by paragraph (3), the following:

''(i) TELEPHONE SERVICE AND DEDICATED EMAIL ADDRESS.—

''(1) IN GENERAL.—A seller of contact lenses who requests verification of any contact lens prescription shall provide—

''(A) a toll-free telephone service that is operable during regular business hours and operated by live persons; and

''(B) a dedicated email address for the sole purpose of responding to prescribers' questions and concerns regarding verification requests.

''(2) CAPACITY.—Such toll-free telephone service shall maintain a sufficient number of working telephone lines operated by live persons to enable ready access by prescribers to the service.''.

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall take effect on the date that is 180 days after the date of the enactment of this Act.

SEC. 3. MODIFICATION OF PROHIBITION ON ALTERATION OF CONTACT LENS PRESCRIPTIONS.

(a) IN GENERAL.—Subsection (f) of section 4 of the Fairness to Contact Lens Consumers Act (15 U.S.C. 7603) is amended to read as follows:

''(f) NO ALTERATION.—

''(1) IN GENERAL.—A seller may not alter a contact lens prescription and when dispensing a contact lens prescription, may only dispense such prescription exactly as written by the prescriber.

''(2) PRIVATE LABELS.—In a case in which a private label contact lens is included on the contact lens prescription and 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 of exactly the same material, design, and power as manufactured by that company under another label.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on the date that is 180 days after the date of the enactment of this Act.

SEC. 4. REQUIREMENTS FOR IMPROVED RECORDKEEPING BY SELLERS OF CONTACT LENSES.

Section 4(b) of the Fairness to Contact Lens Consumers Act (15 U.S.C. 7603(b)) is amended—

(1) by striking ''A seller'' and inserting the following:

''(1) COMMUNICATIONS GENERALLY.—A seller''; and

(2) by adding at the end the following:

''(2) PRESCRIPTIONS.—Each seller shall maintain a database that includes, for each prescription received by a seller, the following:

''(A) The date on which the prescription was issued.

''(B) The specified expiration date of the prescription.

''(3) PREFERRED METHODS OF COMMUNICATION.—For each written notification that a seller receives under subsection (e)(1), the seller shall keep a copy of such notification for a period of not less than 3 years.''.

SEC. 5. PROHIBITION ON REPRESENTATION IN ADVERTISING THAT PRESCRIPTIONS FOR CONTACT LENSES MAY BE FILLED AFTER EXPIRATION DATE.

Section 6 of the Fairness to Contact Lens Consumers Act (15 U.S.C. 7605) is amended—

(1) by striking ''that contact'' and inserting the following: ''that—

''(1) contact'';

(2) in paragraph (1), as designated by paragraph (1) of this section, by striking the period at the end and inserting ''; or''; and

(3) by adding at the end the following:

''(2) a prescription for a contact lens may be filled after the expiration date of the prescription.''.

SEC. 6. INCREASED PENALTIES FOR SELLERS OF CONTACT LENSES WHO VIOLATE REQUIREMENTS RELATING TO PRESCRIBER VERIFICATION.

(a) IN GENERAL.—Subsection (b) of section 9 of the Fairness to Contact Lens Consumers Act (15 U.S.C. 7608) is amended by striking the period at the end and inserting '', except that fines imposed for a violation of section 4 of this Act may be in an amount up to $40,000 per violation.''.

(b) CLARIFICATION OF APPLICABILITY.—Such section is further amended by adding at the end the following new subsection:

''(c) APPLICABILITY.—This chapter shall apply to all sales of contact lenses in the United States and the sellers involved in such sales, notwithstanding where the seller is located.''.

SEC. 7. CONTACT LENS CONSUMER COMPLIANCE AND SAFETY STUDY.

(a) STUDY REQUIRED.—The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention, shall conduct a study to examine the adverse and potentially adverse effects on consumers of violations by sellers of the Fairness to Contact Lens Consumers Act (15 U.S.C. 7601 et seq.), as amended by section 2, particularly with respect to matters regarding prescription verification, business practices, and enforcement by the Federal Trade Commission of such Act.

(b) ELEMENTS.—The study required by subsection (a) shall specifically address the following:

(1) The overfilling of prescriptions with quantities of lenses such that the normal expiration dates of the prescriptions will be exceeded.

(2) The dispensing of prescriptions that have expired or are inaccurate.

(3) The failure by a seller to allow prescribers to contact the seller within 8 business hours to advise that a prescription is inaccurate or expired.

(4) The health risks to the consumer of receiving an incorrect prescription from a seller, or issues with patient access to the medically prescribed contact lenses.

(5) The economic risks to the consumer of receiving an incorrect prescription from a seller.

(6) The improper advertising to consumers about what constitutes a valid prescription or valid prescription information, or advertising that no prescription is needed.

(7) Such other matters regarding the effects on the health of the consumers from violations of the verification or sales requirements of the Fairness to Contact Lens Consumers Act (15 U.S.C. 7601 et seq.) as the Secretary considers appropriate.

(c) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall submit to Congress and the Federal Trade Commission a report on the study required by subsection (a).

SEC. 8. MODIFICATION OF DEFINITIONS.

(a) IN GENERAL.—Section 11 of the Fairness to Contact Lens Consumers Act (15 U.S.C. 7610) is amended—

(1) in paragraph (3), by amending subparagraph (E) to read as follows:

"(E) Power, material, manufacturer, or device name."; and

(2) by adding at the end the following:

"(4) BUSINESS HOUR.—The term 'business hour' means, with respect to a prescriber, any hour during a business day within the period beginning at 9:00 in the morning and ending at 5:00 in the evening in the time zone of the prescriber.

"(5) BUSINESS DAY.—The term 'business day' means any day other than Saturday and Sunday and other than a legal holiday (within the meaning of section 7503 of the Internal Revenue Code of 1986).".

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall take effect on the date that is 180 days after the date of the enactment of this Act.

○