State of Minnesota

HOUSE OF REPRESENTATIVES

NINETY-FIRST SESSION

H. F. No. 485

01/28/2019 Authored by Howard, Cantrell, Mann, Masin, Halverson and others
The bill was read for the first time and referred to the Committee on Health and Human Services Policy
02/07/2019 By motion, recalled and re-referred to the Committee on Commerce
03/11/2019 Adoption of Report: Amended and re-referred to the Committee on Health and Human Services Policy

A bill for an act

relating to human services; establishing the pharmaceutical assistance program; establishing the insulin assistance account in the special revenue fund; establishing fees and penalties; appropriating money; amending Minnesota Statutes 2018, sections 147.37; 151.06, by adding a subdivision; 151.252, subdivision 1; proposing coding for new law in Minnesota Statutes, chapters 148; 151; 256.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. **CITATION.**

This act may be cited as "The Alec Smith Emergency Insulin Act."

Sec. 2. Minnesota Statutes 2018, section 147.37, is amended to read:

147.37 INFORMATION PROVISION; PHARMACEUTICAL ASSISTANCE PROGRAMS.

At least annually, the board shall encourage licensees who are authorized to prescribe drugs to make available to patients information on ~~free and discounted prescription drug programs offered by pharmaceutical manufacturers when the information is provided to the licensees at no cost~~ sources of lower cost prescription drugs and shall provide these licensees with the address for the website established by the Board of Pharmacy pursuant to section 151.06, subdivision 6.

Sec. 3. **[148.192] INFORMATION PROVISION; PHARMACEUTICAL ASSISTANCE PROGRAMS.**

At least annually, the board shall encourage licensees who are authorized to prescribe drugs to make available to patients information on sources of lower cost prescription drugs

and shall provide these licensees with the address for the website established by the Board of Pharmacy pursuant to section 151.06, subdivision 6.

Sec. 4. Minnesota Statutes 2018, section 151.06, is amended by adding a subdivision to read:

Subd. 6. **Information provision; sources of lower cost prescription drugs.** (a) The board shall publish a page on its website that provides regularly updated information concerning:

(1) pharmaceutical manufacturer patient assistance programs;

(2) the prescription drug assistance program established by the Minnesota Board of Aging under section 256.975, subdivision 9;

(3) the emergency insulin assistance program established under section 256.937;

(4) the websites through which individuals can access information concerning eligibility for and enrollment in Medicare, medical assistance, MinnesotaCare, and other government-funded programs that help pay for the cost of health care;

(5) the program established under section 340b of the federal Public Health Services Act, United States Code, title 42, section 256b; and

(6) any other resource that the board deems useful to individuals who are attempting to purchase prescription drugs at lower costs.

(b) The board shall prepare educational documents and materials, including brochures and posters, based on the information it provides on its website under paragraph (a). The documents and materials shall be in a form that can be downloaded from the board's website and used for patient education by pharmacists and by practitioners who are licensed to prescribe. The board is not required to provide printed copies of these documents and materials.

(c) At least annually, the board shall encourage licensed pharmacists and pharmacies to make available to patients information on sources of lower cost prescription drugs and shall provide these licensees with the address for the website established under paragraph (a).

Sec. 5. Minnesota Statutes 2018, section 151.252, subdivision 1, is amended to read:

Subdivision 1. **Requirements.** (a) No person shall act as a drug manufacturer without first obtaining a license from the board and paying any applicable fee specified in section 151.065.

(b) In addition to the license required under paragraph (a), a manufacturer of insulin must pay the applicable insulin registration fee in section 151.254, by June 1 of each year, beginning June 1, 2020. In the event of a change of ownership of the manufacturer, the new owner must pay the registration fee in section 151.254 that the original owner would have been assessed had it retained ownership. The board may assess a late fee of ten percent per month for any portion of a month that the registration fee is paid after the due date. The registration fee collected under this paragraph, including any late fees, shall be deposited in the insulin assistance account established under section 256.938.

~~(b)~~ (c) Application for a drug manufacturer license under this section shall be made in a manner specified by the board.

~~(c)~~ (d) No license shall be issued or renewed for a drug manufacturer unless the applicant agrees to operate in a manner prescribed by federal and state law and according to Minnesota Rules.

~~(d)~~ (e) No license shall be issued or renewed for a drug manufacturer that is required to be registered pursuant to United States Code, title 21, section 360, unless the applicant supplies the board with proof of registration. The board may establish by rule the standards for licensure of drug manufacturers that are not required to be registered under United States Code, title 21, section 360.

~~(e)~~ (f) No license shall be issued or renewed for a drug manufacturer that is required to be licensed or registered by the state in which it is physically located unless the applicant supplies the board with proof of licensure or registration. The board may establish, by rule, standards for the licensure of a drug manufacturer that is not required to be licensed or registered by the state in which it is physically located.

~~(f)~~ (g) The board shall require a separate license for each facility located within the state at which drug manufacturing occurs and for each facility located outside of the state at which drugs that are shipped into the state are manufactured.

~~(g)~~ (h) The board shall not issue an initial or renewed license for a drug manufacturing facility unless the facility passes an inspection conducted by an authorized representative of the board. In the case of a drug manufacturing facility located outside of the state, the board may require the applicant to pay the cost of the inspection, in addition to the license fee in section 151.065, unless the applicant furnishes the board with a report, issued by the appropriate regulatory agency of the state in which the facility is located or by the United States Food and Drug Administration, of an inspection that has occurred within the 24 months immediately preceding receipt of the license application by the board. The board

may deny licensure unless the applicant submits documentation satisfactory to the board that any deficiencies noted in an inspection report have been corrected.

Sec. 6. **[151.254] INSULIN REGISTRATION FEE.**

Subdivision 1. **Definition.** (a) For purposes of this section, the following terms have the meanings given them.

(b) "Manufacturer" means a manufacturer licensed under section 151.252 engaged in the manufacturing of insulin.

(c) "Wholesaler" means a wholesale drug distributor licensed under section 151.47 and engaged in the wholesale drug distribution of insulin.

Subd. 2. **Reporting requirements.** (a) Effective March 1 of each year, beginning March 1, 2020, each manufacturer and each wholesaler must report to the Board of Pharmacy every sale, delivery, or other distribution within or into the state of insulin that was made to any practitioner, pharmacy, hospital, or other person who is permitted by section 151.37 to possess insulin for administration or was dispensed to human patients during the previous calendar year. Reporting must be in a manner specified by the board. If the manufacturer or wholesaler fails to provide information required under this paragraph on a timely basis, the board may assess an administrative penalty of $100 per day. This penalty shall not be considered a form of disciplinary action. Any penalty assessed under this section shall be deposited in the insulin assistance account established under section 256.938.

(b) By March 1 of each year, beginning March 1, 2020, each owner of a pharmacy with at least one location within this state must report to the board any intracompany delivery or distribution of insulin into this state, to the extent that those deliveries and distributions are not reported to the board by a licensed wholesaler owned by, under contract to, or otherwise operating on behalf of the owner of the pharmacy. Reporting must be in the manner and format specified by the board for deliveries and distributions that occurred during the previous calendar year. The report must include the name of the manufacturer or wholesaler from which the owner of the pharmacy ultimately purchased the insulin and the amount and date the purchase occurred.

Subd. 3. **Determination of manufacturer's registration fee.** (a) The board shall annually assess manufacturers a registration fee that in aggregate equals the total cost of the insulin assistance program established under section 256.937 for the previous fiscal year, including any administration costs incurred by the commissioner of human services or the board in collecting the fee. The board shall determine each manufacturer's annual insulin registration

fee that is prorated and based on the manufacturer's percentage of the total number of units reported to the board under subdivision 2. For the first assessment, the commissioner shall estimate the cost of the program for the first fiscal year and notify the board of the estimated cost by March 1, 2020. The board shall determine each manufacturer's initial registration fee based on the estimated cost.

(b) By April 1 of each year, beginning April 1, 2020, the board shall notify each manufacturer of the annual amount of the manufacturer's insulin registration fee to be paid in accordance with section 151.252, subdivision 1, paragraph (b).

(c) A manufacturer may dispute the fee assessed under this section as determined by the board no later than 30 days after the date of notification. However, the manufacturer must still remit the registration fee required by section 151.252, subdivision 1, paragraph (b). The dispute must be filed with the board in the manner and using the forms specified by the board. A manufacturer must submit, with the required forms, data satisfactory to the board that demonstrates that the fee was incorrect or otherwise unwarranted. The board must make a decision concerning a dispute no later than 60 days after receiving the required dispute forms. If the board determines that the manufacturer has satisfactorily demonstrated that the original fee was incorrect, the board must: (1) adjust the manufacturer's fee; (2) adjust the manufacturer's fee due the next year by the amount in excess of the correct fee that should have been paid; or (3) refund the amount paid in error.

Sec. 7. **[256.937] INSULIN ASSISTANCE PROGRAM.**

Subdivision 1. **Establishment.** (a) The commissioner of human services shall implement an insulin assistance program by July 1, 2020. Under the program, the commissioner shall:

(1) pay participating pharmacies for insulin that is dispensed by a participating pharmacy to an eligible individual subject to a valid prescription;

(2) maintain an up-to-date list of eligible individuals and make the list available to participating pharmacies; and

(3) ensure pharmacy participation in the program in all areas of the state and maintain an up-to-date list of participating pharmacies on the department's website.

(b) The commissioner may contract with a private entity or enter into an interagency agreement with another state agency to implement this program.

Subd. 2. **Eligible individual.** (a) To be eligible for the insulin assistance program, an individual must submit to the commissioner an application form that is signed by the individual. To be eligible, an individual must:

(1) be a resident of Minnesota;

(2) not be eligible for Medicare, medical assistance, or MinnesotaCare;

(3) have a family income that is equal to or less than 400 percent of the federal poverty guidelines; and

(4) be uninsured, have no prescription drug coverage, or be covered by an individual or group health plan with an out-of-pocket limit of $5,000 or greater.

(b) The commissioner shall develop an application form and make the form available to pharmacies, health care providers, and to individuals on the department's website. An applicant must include their income and insurance status information with the application. The commissioner may require the applicant to submit additional information to verify eligibility if deemed necessary by the commissioner.

(c) Upon receipt of a completed application and any additional information requested by the commissioner, the commissioner shall determine eligibility to the program. Once the individual has been determined eligible, the individual shall be issued an identification card. The card shall be valid for 90 days from the date of issuance and may be used at any participating pharmacy. An individual is not eligible for renewal until 12 months from the card's expiration date, at which time the individual must submit a new application form and meet the qualifications in paragraph (a).

Subd. 3. **Pharmacy participation.** (a) Pharmacy participation in the program is voluntary. In order to participate, a pharmacy must register with the commissioner and agree to reimbursement and other contract terms. A pharmacy may withdraw from participation at any time by providing written notice to the commissioner.

(b) A pharmacy shall dispense insulin to eligible individuals who present a valid prescription and an identification card.

(c) Eligible individuals are responsible for paying an insulin co-payment to the participating pharmacy that is equal to the prescription co-payment required under section 256L.03, subdivision 5.

(d) Notwithstanding paragraph (c), if an eligible individual has coverage through an individual or group health plan, the pharmacy must process the insulin in accordance with the individual's health plan.

(e) When dispensing insulin to an eligible individual, a pharmacy must provide the individual with the address for the website established under section 151.06, subdivision 6, paragraph (a).

Sec. 8. **[256.938] INSULIN ASSISTANCE ACCOUNT.**

Subdivision 1. **Establishment.** The insulin assistance account is established in the special revenue fund in the state treasury. The fees collected by the Board of Pharmacy under section 151.252, subdivision 1, paragraph (b), shall be deposited into the account.

Subd. 2. **Use of account funds.** For fiscal year 2021 and subsequent fiscal years, money in the insulin assistance account is appropriated to the commissioner of human services to fund the insulin assistance program established under section 256.937.