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

A bill for an act

relating to human services; establishing an insulin assistance program; establishing the insulin assistance account in the special revenue fund; requiring drug manufacturers to pay an insulin product fee; providing for emergency refills; appropriating money; amending Minnesota Statutes 2018, sections 151.252, subdivision 1; 151.37, by adding a subdivision; proposing coding for new law in Minnesota Statutes, chapters 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 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) Application for a drug manufacturer license under this section shall be made in a manner specified by the board.

(c) 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) 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) 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) 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) 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.

(h) The board shall not issue a renewed license for a drug manufacturer unless the manufacturer pays any insulin product fee it is required to pay under section 151.2521.

Sec. 3. **[151.2521] INSULIN PRODUCT FEE.**

Subdivision 1. **Insulin product fee established.** (a) A manufacturer licensed under section 151.252 that holds a Food and Drug Administration approved New Drug Application, or approved Abbreviated New Drug Application, for any qualified insulin product, shall pay to the Board of Pharmacy an insulin product fee as specified in this section.

(b) For purposes of this section, a "qualified insulin product" means any prescription product containing insulin for which the board determines the wholesale acquisition cost of the drug, or other relevant measure of drug cost, exceeds the national average for comparable prescription products containing insulin.

Subd. 2. **Reporting requirements.** (a) Effective December 1, 2019, a manufacturer licensed under section 151.252 shall provide the board with data about each of its prescription

products that contain insulin that are sold within this state. The data shall include, for each product, the trade and generic names, strength, package size, and National Drug Code. A manufacturer required to report this data shall also report a billing address to which the board can send invoices and inquiries related to the insulin product fee. A manufacturer shall notify the board of any change to this data no later than 30 days after the change is made. The board may require a manufacturer to confirm the accuracy of the data on a quarterly basis. If a manufacturer 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.

(b) Effective February 1, 2020, a manufacturer licensed under section 151.252 or a wholesaler licensed under section 151.47 shall report to the board every sale, delivery, or other distribution within or into this state of any prescription product containing insulin that is made to any practitioner, pharmacy, or hospital. Reporting shall be in the Automation of Reports and Consolidated Orders System format unless otherwise specified by the board, and shall occur by the 15th day of each calendar month, for sales, deliveries, and other distributions that occurred during the previous calendar month, except that the first report submitted to the board shall include data retroactive to July 1, 2019. If a 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.

(c) Effective February 1, 2020, any pharmacy licensed under section 151.19 and located outside of this state, including but not limited to community, long-term care, mail order, and compounding and central service pharmacies, must report the dispensing of prescription products that contain insulin to patients located within this state. Reporting shall be in the manner and format specified by the board, and shall occur by the 15th day of each month, for dispensing that occurred during the previous calendar month, except that the first report submitted to the board shall include data retroactive to July 1, 2019. If a pharmacy 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.

(d) Effective February 1, 2020, the owners of pharmacies that are located within this state must report the intracompany delivery or distribution, into this state, of the drugs described in subdivision 1, 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 pharmacies. Reporting shall be in the manner and format

specified by the board, and shall occur by the 15th day of each month, for deliveries and distributions that occurred during the previous calendar month, except that the first report submitted to the board shall include data retroactive to July 1, 2019.

Subd. 3. **Invoicing and payment.** (a) The board, beginning January 1, 2020, and at least quarterly thereafter, shall use the data submitted under subdivision 2 to identify qualified insulin products and prepare invoices for each manufacturer that is required to pay an insulin product fee for a qualified insulin product, as required by this section. The invoices for each quarter shall be prepared and sent to manufacturers no later than 30 days after the end of each quarter, except that the first invoice prepared by the board shall be for the first three quarters of fiscal year 2020. Manufacturers shall remit payment to the board by no later than 30 days after the date of the invoice. If a manufacturer fails to remit payment by that date, the board shall charge interest at the rate that manufacturers are charged interest for making late Medicaid rebate payments.

(b) A manufacturer may dispute the amount invoiced by the board no later than 30 days after the date of the invoice. However, the manufacturer must still remit payment for the amount invoiced as required by this section. The dispute shall 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 original amount invoiced was incorrect. The board shall make a decision concerning a dispute no later than 60 days after receiving the required forms. If the board determines that the manufacturer has satisfactorily demonstrated that the original fee invoiced by the board was incorrect, the board shall reimburse the manufacturer for any amount that is in excess of the correct amount that should have been invoiced. The board shall make this reimbursement when it notifies the manufacturer of its decision.

Subd. 4. **Calculation of fees.** The board shall calculate the fee that is to be paid by using a base rate for all qualified insulin products, equal to $..... per unit, as defined by the board, distributed or dispensed.

Subd. 5. **Deposit of fees.** The board shall deposit all fees collected under this section into the insulin assistance account established under section 151.256.

Sec. 4. **[151.256] 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 151.2521 shall be deposited into the account.

Subd. 2. **Use of account funds.** For fiscal year 2020 and subsequent fiscal years, money in the insulin assistance account is appropriated to the commissioner of administration to fund the insulin assistance program established under section 256.042.

Sec. 5. Minnesota Statutes 2018, section 151.37, is amended by adding a subdivision to read:

Subd. 2b. **Emergency prescription refills.** (a) A pharmacist may dispense a prescription drug, other than a schedule II controlled substance, without a written or oral prescription from a licensed health professional authorized to prescribe drugs, if all of the following conditions are met:

(1) the pharmacy at which the pharmacist works has a record of the prescription for the drug in the name of the patient who is requesting it, but the prescription does not provide for a refill or the time permitted for providing refills has elapsed;

(2) the pharmacist is unable to obtain authorization to refill the prescription from the health care professional who issued the prescription or another health professional responsible for the patient's care; and

(3) in the exercise of the pharmacist's professional judgment:

(i) the drug is essential to sustain the life of the patient or continue therapy for a chronic condition of the patient; and

(ii) failure to dispense or sell the drug to the patient could result in harm to the health of the patient.

(b) The amount of the drug that may be dispensed or sold under this section shall not exceed a 72-hour supply.

Sec. 6. **[256.042] INSULIN ASSISTANCE PROGRAM.**

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

(1) reimburse pharmacies for insulin products and related supplies that are dispensed by the pharmacy to qualified individuals subject to a valid prescription;

(2) accept statements of financial need from persons seeking to participate in the program as qualified individuals, and maintain an up-to-date list of qualified individuals on the agency website, that is available to participating pharmacies; and

(3) seek participation in the program by pharmacies in all areas of the state, and maintain an up-to-date list of participating pharmacies on the agency website, that is available to qualified individuals.

Subd. 2. **Qualified individual.** For purposes of this section, a "qualified individual" is an individual who:

(1) does not have health coverage through medical assistance, MinnesotaCare, or a health plan, as defined in section 62Q.01, subdivision 3; and

(2) submits to the commissioner a completed statement of financial need that has been signed by the individual, and a physician or other health care professional who has issued a prescription for insulin products to the individual.

Subd. 3. **Statement of financial need.** (a) The commissioner shall develop a statement of financial need, and make this form available to health care professionals and individuals on the agency website. The form must:

(1) state that the individual signing the form requires insulin products and related supplies to avoid serious health complications;

(2) state that the individual signing the form has attested, to the physician or health professional writing the prescription for insulin products and related supplies, that the individual lacks the financial means to pay for these items, and does not have health coverage through medical assistance, MinnesotaCare, or a health plan, as defined in section 62Q.01, subdivision 3; and

(3) provide for the signature of both the individual and the physician or health care professional.

(b) In order to participate in the program, an individual must submit the completed form to the commissioner, and must submit a paper or electronic copy of the form to a participating pharmacy when initially filling the prescription. An individual is eligible for the program for 90 days, beginning on the date the form is completed and signed. An individual may renew participation for additional 90-day periods, but must submit a new form to the commissioner and participating pharmacy for each additional 90-day period of program participation.

Subd. 4. **Pharmacy participation.** 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 shall dispense insulin products and related supplies to qualified individuals who present a valid prescription and either are on

the list of qualified individuals maintained by the commissioner or, when initially filling a prescription, present a completed statement of financial need that has not expired. Insulin products and related supplies shall be dispensed at no cost to a qualified individual. When dispensing insulin products and related supplies to a qualified individual, a pharmacy must provide the qualified individual with information about any relevant drug manufacturer patient discount programs, and contact information for local navigator or in-person assister programs established under section 62V.05, subdivision 4.