SENATE
STATE OF MINNESOTA
THIRD SPECIAL SESSION

S.F. No. 17

(SENATE AUTHORS: LITTLE)

DATE	D-PG	OFFICIAL STATUS
08/12/2020		Introduction and first reading Referred to Rules and Administration

A bill for an act

relating to health care; establishing an insulin registration fee; modifying the Alec Smith Insulin Affordability Act; appropriating money; amending Laws 2020, chapter 73, section 4, subdivisions 3, as amended, 6.

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

Section 1. Laws 2020, chapter 73, section 4, subdivision 3, as amended by Laws 2020, chapter 115, article 3, section 37, is amended to read:

Subd. 3. **Access to urgent-need insulin.** (a) MNsure shall develop an application form to be used by an individual who is in urgent need of insulin. The application must ask the individual to attest to the eligibility requirements described in subdivision 2. The form shall be accessible through MNsure's website. MNsure shall also make the form available to pharmacies and health care providers who prescribe or dispense insulin, hospital emergency departments, urgent care clinics, and community health clinics. By submitting a completed, signed, and dated application to a pharmacy, the individual attests that the information contained in the application is correct.

(b) If the individual is in urgent need of insulin, the individual may present a completed, signed, and dated application form to a pharmacy. The individual must also:

(1) have a valid insulin prescription; and

(2) present the pharmacist with identification indicating Minnesota residency in the form of a valid Minnesota identification card, driver's license or permit, or tribal identification card as defined in section 171.072, paragraph (b). If the individual in urgent need of insulin is under the age of 18, the individual's parent or legal guardian must provide the pharmacist with proof of residency.

(c) Upon receipt of a completed and signed application, the pharmacist shall dispense the prescribed insulin in an amount that will provide the individual with a 30-day supply. The pharmacy must notify the health care practitioner who issued the prescription order no later than 72 hours after the insulin is dispensed.

(d) The pharmacy may submit to the manufacturer of the dispensed insulin product or to the manufacturer's vendor a claim for payment that is in accordance with the National Council for Prescription Drug Program standards for electronic claims processing, unless the manufacturer agrees to send to the pharmacy a replacement supply of the same insulin as dispensed in the amount dispensed. If the pharmacy submits an electronic claim to the manufacturer or the manufacturer's vendor, the manufacturer or vendor shall reimburse the pharmacy in an amount that covers the pharmacy's acquisition cost.

(e) The pharmacy may collect an insulin co-payment from the individual to cover the pharmacy's costs of processing and dispensing in an amount not to exceed $35 for the 30-day supply of insulin dispensed.

(f) The pharmacy shall also provide each eligible individual with the information sheet described in subdivision 7 and a list of trained navigators provided by the Board of Pharmacy for the individual to contact if the individual is in need of accessing ongoing insulin coverage options, including assistance in:

(1) applying for medical assistance or MinnesotaCare;

(2) applying for a qualified health plan offered through MNsure, subject to open and special enrollment periods;

(3) accessing information on providers who participate in prescription drug discount programs, including providers who are authorized to participate in the 340B program under section 340b of the federal Public Health Services Act, United States Code, title 42, section 256b; and

(4) accessing insulin manufacturers' patient assistance programs, co-payment assistance programs, and other foundation-based programs.

(g) The pharmacist shall retain a copy of the application form submitted by the individual to the pharmacy for reporting and auditing purposes.

(h) A manufacturer may submit to the commissioner of administration a request for reimbursement of payments paid to pharmacies under paragraph (d). The commissioner of administration shall reimburse the manufacturer for each request submitted by the

manufacturer and received by the commissioner. The commissioner shall determine the manner and format for submitting and processing requests for reimbursement.

EFFECTIVE DATE. This section is effective the day following final enactment.

Sec. 2. Laws 2020, chapter 73, section 4, subdivision 6, is amended to read:

Subd. 6. **Continuing safety net program; process.** (a) The individual shall submit to a pharmacy the statement of eligibility provided by the manufacturer under subdivision 5, paragraph (b). Upon receipt of an individual's eligibility status, the pharmacy shall submit an order containing the name of the insulin product and the daily dosage amount as contained in a valid prescription to the product's manufacturer.

(b) The pharmacy must include with the order to the manufacturer the following information:

(1) the pharmacy's name and shipping address;

(2) office telephone number, fax number, e-mail address, and contact name; and

(3) any specific days or times when deliveries are not accepted by the pharmacy.

(c) Upon receipt of an order from a pharmacy and the information described in paragraph (b), the manufacturer shall send to the pharmacy a 90-day supply of insulin as ordered, unless a lesser amount is requested in the order, at no charge to the individual or pharmacy.

(d) Except as authorized under paragraph (e), the pharmacy shall provide the insulin to the individual at no charge to the individual. The pharmacy shall not provide insulin received from the manufacturer to any individual other than the individual associated with the specific order. The pharmacy shall not seek reimbursement for the insulin received from the manufacturer or from any third-party payer.

(e) The pharmacy may collect a co-payment from the individual to cover the pharmacy's costs for processing and dispensing in an amount not to exceed $50 for each 90-day supply if the insulin is sent to the pharmacy.

(f) The pharmacy may submit to a manufacturer a reorder for an individual if the individual's eligibility statement has not expired. Upon receipt of a reorder from a pharmacy, the manufacturer must send to the pharmacy an additional 90-day supply of the product, unless a lesser amount is requested, at no charge to the individual or pharmacy if the individual's eligibility statement has not expired.

(g) Notwithstanding paragraph (c), a manufacturer may send the insulin as ordered directly to the individual if the manufacturer provides a mail order service option.

(h) A manufacturer may submit to the commissioner of administration a request for reimbursement for the insulin provided by the manufacturer in accordance with this subdivision. The amount reimbursed to the manufacturer must be equivalent to the actual acquisition cost of the insulin provided. The commissioner of administration shall reimburse the manufacturer for each request submitted by the manufacturer and received by the commissioner. The commissioner shall determine the manner and format for submitting and processing requests for reimbursement.

EFFECTIVE DATE. This section is effective the day following final enactment.

Sec. 3. **INSULIN REPORTING AND REGISTRATION FEE.**

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

(b) "Board" means the Minnesota Board of Pharmacy established in Minnesota Statutes, section 151.02.

(c) "Manufacturer" means a manufacturer licensed under Minnesota Statutes, section 151.252, and engaged in the manufacturing of insulin.

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

Subd. 2. **Reporting requirements.** (a) By September 1, 2020, each manufacturer and each wholesaler must report to the board every sale, delivery, or other distribution of insulin within or into the state that was made to any practitioner, pharmacy, or other person who is permitted by Minnesota Statutes, section 151.37, to possess insulin for outpatient dispensing to human patients during calendar year 2019. Reporting must be in the manner and format specified by the board.

(b) By September 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 calendar year 2019. 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.

(c) If the manufacturer, wholesaler, or pharmacy fails to provide the information required under this subdivision on a timely basis, the board may assess an administrative penalty of

up to $10,000 per day. This penalty is not considered a form of disciplinary action. Any penalty assessed under this section shall be deposited in the insulin assistance account established under subdivision 5.

Subd. 3. **Determination of manufacturer's registration fee.** (a) The board shall assess manufacturers a onetime registration fee that in aggregate equals a total of $3,000,000. The board shall determine for each manufacturer a prorated insulin registration fee that is based on the manufacturer's percentage of the total number of units reported to the board under subdivision 2.

(b) By November 1, 2020, the board shall notify each manufacturer of the amount of the manufacturer's insulin registration fee to be paid in accordance with subdivision 4.

(c) A manufacturer may dispute the fee assessed under this subdivision as determined by the board no later than 30 days after the date of notification. 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 original fee was correct, the manufacturer must remit the registration fee as required under subdivision 4. 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; and

(2) adjust the fees of other manufacturers as needed to ensure that the registration fee in the aggregate totals the amount specified in paragraph (a).

(d) Notwithstanding paragraph (c), if a manufacturer fails to provide information required under subdivision 2 on a timely basis, the board may set the insulin registration fee for that manufacturer, taking into account that manufacturer's percentage of the total number of units of insulin sold, delivered, or distributed under the medical assistance program during calendar year 2019.

Subd. 4. **Payment of the insulin registration fee.** Each manufacturer must pay to the board the applicable insulin registration fee determined under subdivision 3 by March 1, 2021. In the event of a change in ownership of the manufacturer, the new owner must pay the registration fee determined under subdivision 3 that the original owner would have been assessed had it retained ownership. The board may assess a late fee of ten percent per month or any portion of a month that the registration fee is paid after the due date. The registration

fee collected under this section, including any late fees collected under this section, shall be deposited in the insulin assistance account established in subdivision 5.

Subd. 5. **Insulin assistance account.** (a) The insulin assistance account is established in the special revenue fund in the state treasury. Money in the insulin account is appropriated to the commissioner of administration to reimburse manufacturers for insulin dispensed under the insulin safety net program established under Minnesota Statutes, section 151.74, in accordance with Minnesota Statutes, section 151.74, subdivisions 3, paragraph (h), and 6, paragraph (h), and to cover costs incurred by the commissioner for providing these reimbursement payments.

(b) The commissioner of management and budget shall transfer to the health care access fund up to a total amount of $3,000,000 when there is a balance available in the insulin assistance account.

(c) The commissioner of management and budget may transfer money from the health care access fund to the insulin assistance account if the account has a deficiency.

(d) If there is a surplus in the insulin assistance account at the end of fiscal year 2021, the surplus is appropriated to the board and shall be refunded by the board to the manufacturers proportionally to each manufacturer's share of the total registration fee payment.

EFFECTIVE DATE. This section is effective the day following final enactment.

Sec. 4. **TRANSFER.**

In fiscal year 2021, the commissioner of management and budget shall transfer $3,000,000 from the health care access fund to the insulin assistance fund.

EFFECTIVE DATE. This section is effective the day following final enactment.