..... moves to amend H.F. No. 485, the first engrossment, as follows:

Delete everything after the enacting clause and insert:

"Section 1. **CITATION.**

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

Sec. 2. **[151.245] INSULIN REPORTING AND REGISTRATION FEE.**

Subdivision 1. **Definitions.** (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 the manner and format specified by the board.

(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.

(c) If the manufacturer, wholesaler, or pharmacy fails to provide information required under this section 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.

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 state appropriation to the commissioner of human services for the program and any administrative costs incurred by the commissioner of human services or the board in collecting the fee, plus any outstanding liabilities to the program. The board shall determine for each manufacturer a prorated annual insulin registration fee that is 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 (c).

(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 (c). 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)(i) adjust the manufacturer's fee;

(ii) adjust the manufacturer's fee due the next year by the amount in excess of the correct fee that should have been paid; or

(iii) refund the amount paid in error; and

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

(d) If a manufacturer fails to provide information required under subdivision 2 on a timely basis, the board may set an annual 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 the previous calendar year.

Sec. 3. Minnesota Statutes 2019 Supplement, 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), each manufacturer required to pay the registration fee under section 151.066 must pay the fee 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 specified under section 151.066, subdivision 3, that the original owner would have been assessed had the original owner retained ownership. The registration fee collected under this paragraph shall be deposited in the opiate epidemic response account established under section 256.043.

(c) In addition to the license required under paragraph (a), a manufacturer of insulin must pay the applicable insulin registration fee in section 151.245, 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 151.245 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.

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

~~(d)~~ (e) 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.

~~(e)~~ (f) 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.

~~(f)~~ (g) 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.

~~(g)~~ (h) 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, except a manufacturer of opiate-containing controlled substances shall not be required to pay the fee under section 151.065, subdivision 1, clause (16), or subdivision 3, clause (14), for more than one facility.

~~(h)~~ (i) Prior to the issuance of an initial or renewed license for a drug manufacturing facility, the board may require the facility to pass a current good manufacturing practices 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. 4. **[256.937] EMERGENCY INSULIN ASSISTANCE PROGRAM.**

Subdivision 1. **Establishment.** (a) The commissioner of human services shall implement an emergency insulin assistance program by July 1, 2020. Under the program, the commissioner shall process claims and pay participating pharmacies for insulin that is dispensed by the participating pharmacy to an eligible individual.

(b) The commissioner may contract with a private entity or enter into an interagency agreement with another state agency to implement the program or specific requirements of

the program. If the commissioner contracts with a private entity, the contract must prohibit the use of rebates.

(c) For purposes of this section, "program" means the emergency insulin assistance program established under this section.

Subd. 2. **Eligibility requirements.** (a) To be eligible for the program, an individual must:

(1) be a resident of Minnesota;

(2) have a family income that is equal to or less than 600 percent of the federal poverty guidelines;

(3) be uninsured, have no prescription drug coverage, or have prescription drug coverage through an individual or group health plan with an annual out-of-pocket maximum limit for prescription drugs of $3,000 or greater, or an annual out-of-pocket maximum limit of $5,000 or greater if the health plan does not have a specific out-of-pocket maximum for prescription drugs; and

(4) not have participated in the program within the 12 months preceding the application date.

(b) Eligibility for the program is subject to the limits of available funding.

Subd. 3. **Application.** The commissioner shall develop an application form and make the form available on the department's website to pharmacies, health care providers, and individuals. An applicant must include their income and insurance status information with the application. The application must require the applicant to sign the application attesting that the information contained in the application is correct. The commissioner may require the applicant to submit additional information to verify eligibility if deemed necessary by the commissioner.

Subd. 4. **Pharmacy participation.** (a) An individual may present to a participating pharmacy a completed application form that has been signed by the individual attesting that the information contained in the application is correct.

(b) Upon receipt of a completed and signed application form that indicates that the individual is presumptively eligible for the program, and a valid prescription, the participating pharmacy shall dispense the prescribed insulin in an amount that is equivalent to a 30-day supply of insulin. The participating pharmacy shall submit the individual's completed application form to the commissioner within two business days of receipt, and the commissioner shall determine eligibility in accordance with subdivision 5. An individual

who has been deemed eligible for the program by the commissioner in accordance with subdivision 5, and who presents a valid prescription, may receive up to two additional 30-day supplies of insulin from participating pharmacies during the 90-day period of program eligibility.

(c) Notwithstanding paragraph (b), if an individual presents to a participating pharmacy a completed and signed application indicating that the individual is presumptively eligible but the individual does not have a valid prescription for insulin, the pharmacy shall dispense the insulin in accordance with this subdivision if the conditions described in section 151.211, subdivision 3, paragraph (a), are met.

(d) If an individual presents at any pharmacy licensed under chapter 151, the pharmacy must provide the individual with an application form for the emergency insulin assistance program. If the pharmacy is a participating pharmacy, the pharmacy shall dispense insulin to the individual as required under paragraph (b).

(e) If an individual has prescription drug coverage through an individual or group health plan, the pharmacy must submit the claim to the individual's health carrier as primary coverage before submitting the claim for reimbursement through the program, as secondary coverage. An eligible individual is 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.

(f) 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).

Subd. 5. **Commissioner's duties.** (a) Upon receipt of a completed application from a participating pharmacy under subdivision 4, and any additional information from the individual if requested by the commissioner, the commissioner shall determine if the individual is eligible for the program within 30 days of receiving the application and any additional information. If the individual is determined to be eligible, the commissioner shall enroll the individual in the program. Program eligibility shall extend for a period of 90 days from the date the participating pharmacy received the completed and signed application form from the individual under subdivision 4.

(b) If the individual is determined to be eligible for either medical assistance or MinnesotaCare, the individual shall not be eligible for the emergency insulin assistance program after the initial presumptive eligibility period.

(c) The commissioner shall connect each eligible individual with the social service agency in the county in which the individual resides to assist the individual in exploring long-term insulin coverage options.

Subd. 6. **Report.** By January 15, 2022, and by each January 15 thereafter, the commissioner shall submit a report to the chairs and ranking minority members of the legislative committees with jurisdiction over health and human services policy and finance on the emergency insulin assistance program for the previous fiscal year, including:

(1) the number of individuals who participated in the program;

(2) the cost of the program, specifying the administrative costs;

(3) the number of individuals who were presumptively eligible but determined to be ineligible for the program;

(4) the number of individuals who were presumptively eligible and were determined eligible for public health care programs; and

(5) the number of individuals who reapplied for the program.

Sec. 5. **[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 (c), 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 human services to: (1) fund the emergency insulin assistance program established under section 256.937; and (2) repay the general fund for any appropriation provided to the commissioner to implement the emergency insulin assistance program.

Sec. 6. **EARLIER IMPLEMENTATION DATE FOR THE EMERGENCY INSULIN ASSISTANCE PROGRAM.**

(a) The governor may direct by executive order the commissioner of human services to begin operating the emergency insulin assistance program before the July 1, 2020, implementation date.

(b) If the governor does not issue an executive order under paragraph (a), the commissioner of human services shall implement the program by July 1, 2020, as required under Minnesota Statutes, section 256.937.

Sec. 7. **APPROPRIATION.**

$..... is appropriated in fiscal year 2020 from the general fund to the commissioner of human services to implement the emergency insulin assistance program as required under Minnesota Statutes, section 256.937. In fiscal year 2021, the commissioner of management and budget shall reduce the balance of the insulin assistance account by $..... and repay the general fund for the cost of this appropriation to the commissioner of human services.

Sec. 8. **EFFECTIVE DATE.**

Sections 1 through 7 are effective the day following final enactment."

Amend the title accordingly