

**Subject** Insulin assistance programs

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## **Overview**

This bill establishes the emergency insulin assistance program to provide access to insulin on an emergency basis, and the Minnesota insulin patient assistance program to provide access to insulin on an ongoing basis. Under the emergency program, eligible individuals can receive up to a three-month supply of insulin from a pharmacy. The program is administered by the Commissioner of Administration, who may contract with a third-party administrator. The cost of reimbursing pharmacies for insulin dispensed under the emergency program, and administrative costs for both the emergency program and the Minnesota insulin patient assistance program, are paid for by insulin manufacturers through an insulin registration fee paid to the Board of Pharmacy. Money from the fee is deposited into an insulin assistance account.

Persons who apply for the emergency program are also referred to the Minnesota insulin patient assistance program, which is administered by MNsure. Under this program, eligible individuals can receive without charge three-month supplies of insulin from insulin manufacturer assistance programs. Persons not eligible for the program can receive information about accessing other insurance coverage options. Insulin manufacturers must participate in the program as a condition of doing business in Minnesota.

This bill also sets cost-sharing limits for insulin in the private insurance market, requires notice to be provided prior to the ending of dependent coverage, and includes other provisions related to access to insulin.

## Summary

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1	<b>Emergency insulin assistance program</b>
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Adds § 16B.992.

**Subd. 1. Establishment.** (a) Requires the commissioner of administration to implement and administer an emergency insulin program beginning July 1, 2020, for insulin that is prescribed for self-administration on an outpatient basis.

(b) Defines the following terms: emergency program, Minnesota insulin patient assistance program, and navigator.

**Subd. 2. Contract with third-party administrator.** Allows the commissioner to contract with a third-party administrator and provides that the initial contract is not subject to chapter 16C.06 (state procurement requirements). Requires any contract to:

(1) require the third-party administrator to process insulin claims and pay pharmacies for insulin dispensed at a rate at least equal to the medical assistance rate;

(2) prohibit the use of rebates; and

(3) require the third-party administrator to comply with government data practices requirements, maintain data as private, and not share data without patient consent.

**Subd. 3. Eligibility requirements.** To be eligible for the program, requires individuals to have a valid prescription for insulin and attest to:

(1) being a Minnesota resident;

(2) not being enrolled in MA or MinnesotaCare;

(3) having a tax household income not exceeding 500 percent of the federal poverty guidelines;

(4) being uninsured, having drug coverage through Medicare and having incurred annual out-of-pocket drug costs of over \$1,000, or having private insurance coverage with cost sharing that exceeds \$50 for a month's supply of insulin regardless of the amount or types of insulin needed;

(5) not being eligible to receive insulin through Indian Health Services and not enrolled in TRICARE or drug benefits through the U.S. Department of Veterans Affairs; and

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(6) not having had insulin first dispensed through the program during the 12 months preceding application.

**Subd. 4. Application process.** (a) Requires the MNSure board and the commissioner to develop an application form to be used for this program and the Minnesota insulin patient assistance program. The application must require the applicant to indicate whether insulin is being requested on an emergency basis and provide for the applicant's consent to the transfer of personal data. Requires the application to be made available on MNSure and agency websites and to health care practitioners.

(b) Requires the applicant to submit a signed and dated application to the MNSure board in order to obtain insulin. States that the applicant, by signing the application, is attesting that the information in the application is correct and insulin is needed on an emergency basis. Allows applications for emergency insulin to be submitted through the MNSure website or in paper form through a pharmacy. Provides that an individual is not eligible to reapply, by submitting a new application form, until 12 months have elapsed from the date insulin was first dispensed under the program.

(c) Upon receipt of an application, requires the MNSure board to verify, if applicable, whether 12 months have elapsed from the date insulin was first dispensed, and to provide applicants meeting this criterion, and new applicants, with an identification number indicating that a completed application has been received. This must be provided in a downloadable or electronic format.

**Subd. 5. Pharmacy participation.** (a) Requires pharmacies to participate in the program as a condition of doing business.

(b) Requires pharmacies to dispense up to a three-month supply of insulin to individuals who present a valid prescription, completed application, and MNSure identification number, who have indicated that they need insulin on an emergency basis. Requires pharmacies to dispense insulin in one-month increments upon request. Requires pharmacies to submit claims for reimbursement to the commissioner.

(c) Requires pharmacies to make applications available at each pharmacy location and allows pharmacies to assist applicants in applying for the program.

(d) Requires individuals to pay a \$30 copayment for each month's supply of insulin or a proportional copayment for lesser quantities, regardless of the amount or types of insulin needed.

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(e) Requires pharmacies, when dispensing insulin, to provide the individual with the address for the Board of Pharmacy website on accessing lower cost prescription drugs and information on the Minnesota insulin patient assistance program.

**Subd. 6. State and federal anti-kickback provisions.** (a) Provides that persons or entities participating in or administering the emergency insulin assistance program are not subject to liability under the state's anti-kickback provisions.

(b) Prohibits persons or entities participating in or administering the program from requesting or seeking, or causing another to request or seek, any reimbursement or compensation for which payment may be made under a federal health care program.

**Subd. 7. Report.** Requires the commissioner, in consultation with any third-party administrator, to report to the legislature by January 15, 2022, and each January 15 thereafter, on the emergency insulin assistance program for the previous fiscal year, including the number of individuals who received insulin, the cost of the program (with a separate statement of administrative costs), and the number of individuals who reapplied for the program.

**2 Insulin assistance account**

Adds § 16B.993.

**Subd. 1. Establishment.** Establishes the insulin assistance account in the special revenue fund. Requires manufacturer insulin registration fees collected by the Board of Pharmacy to be deposited into the account.

**Subd. 2. Use of account funds.** For fiscal year 2021 and subsequent fiscal years, appropriates money in the account to: (1) the commissioner of administration to reimburse pharmacies and for administrative costs under the emergency insulin assistance program, including the cost of any contract with a third-party administrator; (2) the MNsure board for administrative costs related to the Minnesota insulin patient assistance program and the emergency insulin assistance program; and (3) the commissioner of human services for administrative costs related to the emergency insulin assistance program and the Minnesota insulin assistance program.

**Subd. 3. Transfers.** Allows the commissioner of management and budget to transfer money from the general fund to the insulin assistance account when that account has a projected cash deficiency. Requires transfers to be included in the determination of manufacturer insulin registration fees and requires the general fund to be repaid as soon as the account has sufficient cash balances.

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3	<p><b>Cost-sharing limit for insulin.</b> Adds § 62Q.491.</p> <p><b>Subd. 1. Applicability.</b> States that the section applies to all health plans that provide coverage for insulin.</p> <p><b>Subd. 2. Limit on cost-sharing.</b> (a) Requires health plans to limit cost-sharing for insulin to no more than \$30 for a month's supply, or proportional cost-sharing for other quantities, regardless of the amount or types of insulin needed.</p> <p>(b) States that the subdivision does not prevent a health plan company from limiting cost-sharing to a lower amount than that specified in paragraph (a).</p> <p>Provides a January 1, 2021 effective date.</p>
4	<p><b>Dependent child notice</b></p> <p>Adds § 62Q.678. Requires group health plans and health plan companies that offer group or individual plans with dependent coverage to provide advance written notice to enrollees with dependent child coverage and to the dependent child, that this coverage ends when the child reaches age 26. Specifies requirements for this notice.</p>
5	<p><b>Minnesota insulin patient assistance program</b></p> <p>Adds § 62V.12.</p> <p><b>Subd. 1. Establishment.</b> Requires the MNsure board to implement and administer the Minnesota insulin patient assistance program beginning July 1, 2020, for insulin that is prescribed for self-administration on an outpatient basis.</p> <p><b>Subd. 2. Eligibility.</b> (a) To be eligible, requires an individual to have a valid prescription for insulin and:</p> <ol style="list-style-type: none"><li>(1) be a Minnesota resident;</li><li>(2) not be enrolled in MA or MinnesotaCare;</li><li>(3) have a tax household income not exceeding 400 percent of the federal poverty guidelines;</li><li>(4) be uninsured, have drug coverage through Medicare and have incurred annual out-of-pocket drug costs of over \$1,000, or have private insurance coverage with cost sharing that exceeds \$50 for a month's supply of insulin, regardless of the amount or types of insulin needed;</li><li>(5) not be eligible to receive insulin through Indian Health Services and not be enrolled in TRICARE or drug benefits through the U.S. Department of Veterans Affairs.</li></ol>

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(b) Defines “navigator” and “program.”

**Subd. 3. Application process; eligibility determination.** (a) Requires the board to make the application form available to pharmacies and health care practitioners, and requires pharmacies to make the application available at each location. Also requires the form to be accessible through the MNsure website. Specifies that applicant may submit a signed and date form to the board through the website, by mail or fax, or in person.

(b) Requires the board to develop and implement a process to determine if an individual is eligible for the program, which may include the use of navigators.

(c) Following receipt of an application, requires the board to determine eligibility as provided in this subdivision. Allows the board to require additional information from an applicant.

(d) Requires the board to first determine, using information provided by the commissioner of human services, if the individual is enrolled in MA or MinnesotaCare. If this is the case, the individual is not eligible to participate in the Minnesota insulin patient assistance program. If this is not the case, the board shall refer the individual to a navigator.

(e) The navigator shall screen referred individuals for program eligibility and shall notify the board for confirmation of eligibility. If the board confirms eligibility, the board shall submit the individual’s patient information to drug manufacturer, inform the individual of eligibility, and provide the individual with an eligibility statement that includes a patient identification number.

(f) If the individual is not found eligible for MA, MinnesotaCare, or the Minnesota insulin patient assistance program, the board shall notify the individual of possible qualification for another insulin coverage option, and provide the individual with information on how to enroll in the coverage option or receive other assistance. Insulin coverage options include, but are not limited to: (1) another insulin manufacturer patient assistance program; (2) qualified health plans offered through MNsure; (3) providers who participate in prescription drug discount programs, including 340b providers; and (4) community health centers.

(g) Provides that an eligibility statement is valid for 12 months, after which an individual must submit a new application.

(h) Requires the MNsure board to allow appeals of eligibility determinations using the process provided in Minnesota Rules.

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**Subd. 4. Submittal to manufacturers.** (a) Requires the board to submit the eligible patient's identification number and other relevant information to drug manufacturers according to this section. Specifies applicant notice requirements.

(b) Allows patients in the program to elect to receive insulin from the manufacturer assistance program through a community pharmacy, mail-order pharmacy, or designated health care provider.

**Subd. 5. Manufacturer's responsibilities.** (a) Requires insulin manufacturers to participate in the program as a condition of doing business, and to operate a patient insulin assistance program that meets the requirements of this section. Requires each manufacturer to provide the board with contact information for health care practitioners to use in submitting prescription orders to the manufacturer. States that a prescription order includes the patient's name, identification number, prescription, and delivery address.

(b) Requires a manufacturer, upon receipt of a prescription order and other relevant information, to send a three-month supply of insulin, unless a lesser amount is requested, to the designated pharmacy or health care provider, at no charge.

(c) Requires a manufacturer, upon receipt of a reorder, to send an additional three-month supply of the insulin, unless a lesser amount is requested, to the designated pharmacy or health care provider.

(d) Requires manufacturers to annually report to the Board of Pharmacy information on the number of individuals participating, quantity of insulin provided, and other information necessary for the board to verify compliance. Allows the board to assess a manufacturer an administrative penalty of \$100,000 for each month or partial month of non-compliance.

(e) Requires a manufacturer to comply with specified requirements related to data privacy.

**Subd. 6. Data.** (a) Requires all data collected, created, received, maintained, or disseminated by the board related to applicants, eligible individuals, and program participants to be classified as private data on individuals, allows this data to be shared with manufacturers with patient consent to the extent necessary for program operation, and makes the data subject to certain data privacy requirements that apply to MNsure.

(b) Allows the commissioner of human services and the MNsure board to enter into an information-sharing agreement to determine MA and MinnesotaCare

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enrollment status related to the operation of the program. Specifies criteria for the agreement.

**Subd. 7. State and federal anti-kickback provisions.** (a) Provides that persons or entities participating in or administering the Minnesota insulin patient assistance program are not subject to liability under the state's anti-kickback provisions.

(b) Prohibits persons or entities participating in or administering the program from requesting or seeking, or causing another to request or seek, any reimbursement or compensation for which payment may be made under a federal health care program.

**Subd. 8. Report.** (a) Requires the MNsure board to report to the legislature on the status of the program and the number of individuals served, by January 15 of each year beginning January 15, 2021.

(b) Requires the Board of Pharmacy to report to the legislature annually, beginning January 15, 2021, on the number of individuals participating in a drug manufacturer insulin assistance program, the quantity of insulin products provided in the aggregate and through each drug manufacturer program, and an evaluation of the extent to which drug manufacturers comply with the requirements of this section.

**6 Information provision; sources of lower cost prescription drugs**

Amends § 151.06, subd. 6. Requires the Board of Pharmacy to include, on its website page on lower cost prescription drugs, information on the emergency insulin assistance program and the Minnesota insulin patient assistance program.

**7 Insulin reporting and registration fee**

Adds § 151.245.

**Subd. 1. Definitions.** Defines "manufacturer" and "wholesaler."

**Subd. 2. Reporting requirements.** (a) Requires each manufacturer and wholesaler to report to the Board of Pharmacy, beginning March 1, 2021 and each March 1 thereafter, every sale, delivery, or other distribution of insulin within or into the state to a practitioner, pharmacy, or other person permitted to possess insulin for outpatient dispensing, in the manner and format specified by the board.

(b) Requires pharmacies, beginning March 1, 2021 and each March 1 thereafter, to report to the board any intracompany delivery or distribution of insulin into the state, to the extent this is not reported by a licensed wholesaler. Specifies criteria for reporting.



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(c) Allows the board to assess a manufacturer, wholesaler, or pharmacy an administrative penalty of up to \$10,000 per day for noncompliance. States that the penalty is not a form of disciplinary action and requires penalty assessments to be deposited in the insulin assistance account.

**Subd. 3. Determination of manufacturer's registration fee.** (a) Requires the board to annually assess manufacturers a registration fee that in the aggregate, equals the total cost of: (1) the emergency insulin assistance program for the previous fiscal year, including any appropriation to the commissioner of administration to reimburse pharmacies and any administrative costs incurred by the commissioner of administration, the commissioner of human services, and the MNsure board, or incurred by the board of pharmacy in collecting the fee, plus any transfers that have not been repaid to the general fund and outstanding liabilities to the program; and (2) costs incurred by the MNsure board and the commissioner of human services in administering the Minnesota insulin patient assistance program.

Requires the board to determine a pro-rated fee for each manufacturer based on the manufacturer's percentage of the total number of insulin units reported for sale, distribution, or delivery in the state. Directs the commissioner of management and budget to estimate the cost of the programs for the first fiscal year, and notify the board of this estimated cost by May 1, 2020. Requires the board to determine each manufacturer's initial fee based on this estimate.

(b) Requires the board, beginning June 1, 2020, and each June 1 thereafter, to notify each manufacturer of the annual amount of that manufacturer's insulin registration fee.

(c) Allows a manufacturer to dispute the fee that is assessed within 30 days of notification. Specifies related procedures.

(d) If a manufacturer fails to report required information, allows the board to set an annual insulin registration fee based on the manufacturer's percentage of the total number of units of insulin sold, delivered, or distributed under MA.

(e) Requires any surplus from the first assessment of the insulin registration fee to be refunded by the commissioner of administration to manufacturers in proportion to their share of fee payments.

**8 Requirements**

Amends § 151.252, subd. 1. Requires a manufacturer of insulin to pay the applicable insulin registration fee by July 1 of each year, beginning July 1, 2020. Requires the fee to continue to be paid if there is a change in ownership. Allows the board to assess a fee for late payment of ten percent per month or any portion of a month. Requires

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	the registration fee and any late fees to be deposited into the insulin assistance account.
<b>9</b>	<b>Information provision; pharmaceutical assistance programs</b> Amends § 214.122. Requires the board of medical practice and board of nursing to ensure that their licensees are provided with information on the emergency insulin assistance program and the Minnesota insulin patient assistance program.
<b>10</b>	<b>Citation</b> States that this act may be cited as “The Alec Smith Insulin Affordability Act.”
<b>11</b>	<b>Earlier implementation date for insulin assistance programs</b>  (a) Allows the governor, by executive orders, to begin operation of the emergency insulin assistance program and the Minnesota insulin patient assistance program before the July 1, 2020 implementation dates. If the governor issues an executive order, appropriates an amount sufficient for this purpose to the MNsure board, commissioner of administration, and commissioner of human services in fiscal year 2020, from the insulin assistance account  (b) If the governor does not issue executive orders, requires the both insulin assistance programs to be implemented July 1, 2020.
<b>12</b>	<b>Public awareness campaign</b> Requires the MNsure board, in consultation with the commissioner of administration, to conduct a public awareness campaign for the emergency insulin assistance program and the Minnesota insulin patient assistance program.
<b>13</b>	<b>Appropriation</b> (a) Appropriates \$321,000 in fiscal year 2020 from the health care access fund to the commissioner of administration to implement and administer the emergency insulin assistance program, including the cost of any contract with a third-party administrator. States that this is a onetime appropriation.  (b) Appropriates \$250,000 in fiscal year 2020 from the health care access fund to the MNsure board for a public awareness program for the insulin assistance programs. States that this is a onetime appropriation.  (c) Appropriates \$250,000 in fiscal year 2020 and \$250,000 in fiscal year 2021 from the health care access fund to the MNsure board for navigator training related to the insulin assistance programs. States that this appropriation is added to the base.  (d) Appropriates \$26,000 in fiscal year 2020 from the health care access fund to the commissioner of human services for administrative costs related to the Minnesota insulin patient assistance program. States that this is a onetime appropriation.

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Provides that this section is effective the day following final enactment.



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