

Subject Insulin Program
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Overview

This bill establishes the insulin safety net program, to provide insulin to eligible persons on an emergency and ongoing basis, beginning July 1, 2020. Under the urgent-need safety net program, eligible persons can receive a 30-day supply of insulin from pharmacies, and some individuals may be eligible for an additional 30-day supply. Under this program, insulin manufacturers either reimburse pharmacies for the insulin that is dispensed or supply insulin to pharmacies on a replacement basis. Under the continuing safety net program, eligible persons receive up to a 90-day supply of insulin from manufacturers through insulin manufacturer patient assistance programs that must meet state standards. Insulin is provided on an ongoing basis for the 12-month eligibility period and eligibility for the program may be renewed. The bill sunsets the continuing safety net program December 31, 2024, subject to legislative review and a determination by the legislature that the program should be continued. This bill also requires various reports on the safety net program, contains other provisions related to prescription drug access, and requires insurers to provide notice related to the end of coverage for dependent children.

Summary

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| 1 | Citation
States that the act may be cited as the “Alec Smith Insulin Affordability Act.” States that the section is effective the day following final enactment. |
| 2 | Dependent child notice
Adds § 62Q.678.

Requires group health plans and health plan companies that offer group or individual health plans with dependent coverage to provide enrollees with written notice that dependent child coverage ends when the child reaches age 26. Requires the notice to |

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be sent to the enrollee's address at least 60 days before the dependent child reaches age 26. Requires the notice to include the date on which coverage ends and information on accessing the MNsure website.

3 Information provision; sources of lower cost prescription drugs

Amends § 151.06, subd. 6. Requires the Board of Pharmacy to include on its prescription drug cost website information on the insulin safety net program established in section 151.74, including information on how to access the program.

4 Insulin safety net program

Adds § 151.74.

Subd. 1. Establishment. (a) Requires each manufacturer of insulin, by July 1, 2020, to establish procedures to make insulin available in accordance with the section to eligible individuals who are in urgent need of insulin or need access to an affordable insulin supply.

(b) Defines the following terms: manufacturer, MNsure, navigator, and pharmacy.

(c) Allows manufacturers with annual gross revenue of \$2 million or less from insulin sales in Minnesota to request from the Board of Pharmacy a waiver to be exempt from this section.

(d) Exempts an insulin product from this section if the wholesale acquisition cost is \$8 or less per milliliter or applicable National Council for Prescription Drug Plan billing unit, for the entire assessment time period, adjusted annually by the consumer price index.

Subd. 2. Eligibility for urgent-need safety net program. (a) To be eligible for an urgent need supply of insulin, requires an individual to attest to:

(1) being a Minnesota resident;

(2) not being enrolled in MA or MinnesotaCare;

(3) not being enrolled in drug coverage that limits cost-sharing (including copayments, deductibles, or coinsurance) for a 30-day supply of insulin to \$75 or less, regardless of the type or amount of insulin;

(4) not having received an urgent-need supply of insulin within the previous 12 months, unless authorized by subdivision 9; and

(5) being in urgent need of insulin.

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(b) Defines “urgent need of insulin” as having less than a seven-day supply of insulin readily available, and needing insulin to avoid the likelihood of suffering significant health consequences.

Subd. 3. Access to urgent-need insulin. (a) Requires MNsure to develop an application form for individuals in urgent need of insulin, that asks the individual to attest to the eligibility requirements and is accessible through the MNsure website. Also requires MNsure to make the form available to pharmacies and specified health providers. States that individuals, by submitting a completed, signed, and dated application to a pharmacy, attest that the information in the application is correct.

(b) Provides that individuals in urgent need of insulin may present a completed, signed, and dated application form to a pharmacy. Also requires individuals to: (1) have a valid prescription; and (2) present the pharmacist with a valid Minnesota identification card, driver’s license, or permit, indicating Minnesota residency (with the parent or legal guardian being required to provide proof of residency for persons under age 18).

(c) Requires pharmacists, upon receipt of the application, to dispense a 30-day supply of the prescribed insulin, and to notify the prescriber no later than 72 hours after the insulin is dispensed.

(d) Provides that the pharmacy may submit claims for insulin dispensed to the manufacturer or manufacturer’s vendor, that are in accordance with the National Council for Prescription Drug Program standards for electronic claims processing, unless the manufacturer agrees to send the pharmacy a replacement supply for the insulin dispensed. Requires claims to be reimbursed in an amount that covers the pharmacy’s acquisition cost.

(e) Allows the pharmacy to collect a copayment from the individual, not to exceed \$35 for the 30-day supply of insulin.

(f) Requires the pharmacy to provide each individual with the information sheet developed by the Board of Pharmacy under subdivision 7 and a list of trained navigators for the individual to contact for assistance in accessing specified ongoing insulin coverage options.

(g) Requires the pharmacist to retain a copy of the individual’s application form, for reporting and auditing purposes.

Subd. 4. Continuing safety net program; general. (a) Requires each manufacturer to make a patient assistance program that meets the requirements of this section available to any individual who meets the requirements of this

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subdivision. Requires the manufacturer to provide the Board of Pharmacy with information on their assistance program, including contact information for individuals to call for assistance in accessing the program.

(b) To be eligible to participate in an assistance program, requires individuals to:

(1) be a Minnesota resident with a valid Minnesota identification card, driver's license, or permit, that indicates Minnesota residency; requires the parent or legal guardian to provide proof of residency for individuals under the age of 18;

(2) have a family income equal to or less than 400 percent of the federal poverty guidelines;

(3) not be enrolled in MA or MinnesotaCare;

(4) not be eligible to receive health care through a federally funded program or receive drug benefits through the Department of Veterans Affairs; and

(5) not be enrolled in drug coverage through an individual group plan that limits cost-sharing (including copayments, deductibles, or coinsurance) for a 30-day supply of insulin to \$75 or less, regardless of the type or amount of insulin.

(c) Allows an individual enrolled in Medicare Part D to be eligible for an assistance program if the individual has spent \$1,000 on prescription drugs in the current calendar year and meets the requirements of paragraph (b), clauses (1) to (3).

(d) Allows individuals to apply for an assistance program directly to the manufacturer, through the individual's health care practitioner if the practitioner participates, or through contacting a trained navigator for assistance.

Subd. 5. Continuing safety net program; manufacturer's responsibilities. (a)

Upon receipt of an application, requires the manufacturer to process the application and determine eligibility. Specifies requirements and timelines for processing applications and notifying applicants. Allows individuals to appeal determinations of ineligibility.

(b) Requires the manufacturer to provide individuals determined eligible with an eligibility statement or other indication of eligibility. Provides that eligibility is valid for 12 months and is renewable upon a redetermination of eligibility.

(c) Allows manufacturers to serve persons with drug coverage through an individual or group health plan through the manufacturer's copayment assistance program, if the manufacturer determines that an individual's insulin needs are better addressed through that program. Requires the manufacturer to

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inform the individual and provide the necessary coupons for submittal to a pharmacy. States that copayments cannot exceed the amount specified in subdivision 6, paragraph (e).

Subd. 6. Continuing safety net program; process. (a) Requires individuals to submit the statement of eligibility to a pharmacy, and requires pharmacies to then submit an order with the name of the insulin product and daily dosage amount as contained in a valid prescription to the product's manufacturer.

(b) Lists the information that a pharmacy must include with an order to the manufacturer.

(c) Requires manufacturers, upon receipt of an order and related information, to send the pharmacy a 90-day supply of the insulin, unless a lesser amount is requested, at no charge to the individual or pharmacy.

(d) Requires a pharmacy to provide the insulin to the individual at no charge, except for the allowed copayment. Prohibits a pharmacy from providing the insulin received from the manufacturer to any individual other than the individual associated with the order, and prohibits a pharmacy from seeking reimbursement for the insulin received from the manufacturer or any third-party payer.

(e) Allows the pharmacy to collect from the individual a copayment not to exceed \$50 for each 90-day supply of insulin, if the insulin is sent to the pharmacy.

(f) Allows pharmacies to submit to manufacturers reorders for additional supplies of insulin. Requires manufacturers to provide additional 90-day supplies of insulin, unless a lesser amount is requested, at no charge to the individual or pharmacy, if an individual's eligibility statement has not expired.

(g) Allows a manufacturer to send insulin directly to the individual, if the manufacturer provides a mail order service option.

Subd. 7. Board of pharmacy and MNsure responsibilities. (a) Requires the Board of Pharmacy to develop an information sheet to post on its website and provide this link to pharmacies and health care providers. Requires the information sheet to contain information on the urgent-need insulin safety net program, manufacturer assistance programs, and other specified information related to access to insulin.

(b) Requires the board to inform program participants about the Department of Health satisfaction survey and information on how to participate.

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(c) Requires MNsure, in consultation with the Board of Pharmacy and the commissioner of human services, to develop a training program for navigators related to assisting individuals with accessing long-term insulin options.

(d) Requires MNsure, in consultation with the Board of Pharmacy, to compile and make available a list of navigators who have completed the training program and can assist individuals in accessing affordable insulin coverage options.

(e) Requires MNsure, within the available appropriation, to pay navigators who assist an individual in accessing an insulin manufacturer's patient assistance program with a onetime application assistance bonus of no less than \$25. This payment shall not apply if a navigator receives an assistance bonus under section 62V.05, subdivision 4 or 256.962, subdivision 5.

Subd. 8. Dispute resolution. Allows individuals who disagree with a manufacturer's determination of eligibility to contact the Board of Pharmacy to request use of a three-person panel to review eligibility. Specifies requirements and procedures for the panel and states that a decision of the panel is final.

Subd. 9. Additional 30-day urgent-need insulin supply. Allows individuals to access an additional 30-day supply of urgent-need insulin if the individual: (1) has applied for MA or MinnesotaCare but has not been determined eligible or has been determined eligible but coverage has not become effective; or (2) has been determined ineligible for a manufacturer's assistance program and the individual has requested a review under subdivision 8 but the panel has not rendered a decision. Specifies related requirements.

Subd. 10. Penalty. (a) Allows the Board of Pharmacy to assess a manufacturer an administrative penalty of \$200,000 per month of noncompliance with the requirements of this section, with the penalty increasing to \$400,000 per month after six months, and to \$600,000 per month after one year.

(b) Provides that a manufacturer is also subject to the administrative penalties in paragraph (a) if the manufacturer fails to: (1) provide a hotline meeting certain criteria that individuals can access; and (2) list on its website the eligibility criteria for its patient assistance programs for Minnesota residents.

(c) Requires penalties to be deposited in a separate insulin assistance account in the special revenue fund.

Subd. 11. Data. (a) Classifies data related to individuals seeking to access urgent-need insulin or participate in a manufacturer's assistance program as private data, and prohibits retention of this data for longer than ten years.

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(b) Requires a manufacturer to maintain the privacy of data received from individuals and prohibits selling, sharing, or disseminating the data unless required under this section or the individual has provided signed authorization.

Subd. 12. State and federal antikickback provisions. (a) Provides liability from the state antikickback law for persons or entities participating in or administering the insulin safety net program.

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

Subd. 13. Reports. (a) By February 15 of each year, beginning February 15, 2021, requires manufacturers to report to the Board of Pharmacy on: (1) the number of Minnesota residents who accessed and received insulin on a urgent-need basis in the preceding calendar year; (2) the number of Minnesota residents participating in the manufacturer's patient assistance program in the preceding calendar year, including the number of persons determined ineligible; and (3) the value of the insulin provided under clauses (1) and (2).

(b) By March 15 of each year, beginning March 15, 2021, requires the Board of Pharmacy to submit the information reported under paragraph (a) to the legislature, and to include in this report information on administrative penalties assessed.

Subd. 14. Program review; legislative auditor. (a) Requests the legislative auditor to conduct a program review to determine whether manufacturers are meeting their responsibilities under this section and whether the training program for navigators is adequate and accessible and there is a sufficient number of trained navigators.

(b) Allows the legislative auditor to access application forms retained by pharmacies, to determine whether urgent-need insulin is being dispensed according to this section.

Subd. 15. Program satisfaction; surveys. Requires the commissioner of health, in consultation with the Board of Pharmacy and individuals who are insulin-dependent, to survey individuals and pharmacies participating in the urgent-need and manufacturer assistance programs, on specified aspects of program satisfaction. Allows the commissioner to contract with a nonprofit entity to develop and conduct the survey and evaluate results. Requires the commissioner to report results to the legislature by January 15, 2022.

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Subd. 16. Legislative review; sunset. (a) Requires the legislature to review reports from the Board of Pharmacy under subd. 13, paragraph (b), the legislative auditor under subd. 14, the commissioner of health under subd. 15, paragraph (e), and other relevant information on the cost, access, and affordability of insulin, and make a determination on whether there is a need to continue the long-term safety net program described in subdivisions 4 to 6 to ensure Minnesota residents have access to affordable emergency and long-term insulin, or whether the market has sufficiently changed to where continuation is not needed past December 31, 2024, or whether there are more appropriate options available to ensure access to affordable insulin.

(b) States that subdivision 4 to 6, 8, and 9 expire December 31, 2024, unless the legislature affirmatively determines the need for continuation of the long-term safety net program described in subdivisions 4 to 6.

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

5 Information provision; pharmaceutical assistance program

Amends § 214.122. Requires the boards of medical practice and nursing to ensure that licensees are provided with information on the insulin safety net program and a link to the Board of Pharmacy's information sheet on how patients can apply for the program.

6 Public awareness campaign

Requires the MNsure board to conduct a public awareness campaign related to the insulin safety net program, including how to access insulin if an individual is in urgent need, and the availability of insulin manufacturer patient assistance programs. States that this section is effective the day following final enactment.

7 Severability

Provides a severability clause. States that this section is effective the day following final enactment.

8 Appropriation

(a) Appropriates \$297,000 in fiscal year 2020 from the health care access fund to the MNsure board, with \$108,000 of this amount to train navigators and \$189,000 to provide application assistance bonus payments. States that is a onetime appropriation available until December 31, 2024.

(b) Appropriates \$250,000 in fiscal year 2020 from the health care access fund to the MNsure board for a public awareness campaign. States that this is a onetime appropriation available until December 31, 2024.

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(c) Appropriates \$76,000 in fiscal year 2021 from the health care access fund to the Board of Pharmacy to implement the insulin safety net program. Specifies the base as \$76,000 per year for fiscal years 2022 through 2024, \$38,000 in fiscal year 2025, and \$0 in fiscal year 2026.

(d) Appropriates \$136,000 in fiscal year 2021 from the health care access fund to the commissioner of health to implement the program satisfaction survey. Specifies the base as \$80,000 in fiscal year 2022 and \$0 in fiscal year 2023. States that this is a onetime appropriation.

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

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