

HOUSE OF REPRESENTATIVES

NINETY-FIRST SESSION

H. F. No. **3100**

- 02/11/2020 Authored by Howard, Hortman, Liebling, Wolgamott, Winkler and others
The bill was read for the first time and referred to the Committee on Commerce
- 02/13/2020 Adoption of Report: Re-referred to the Committee on Health and Human Services Policy
- 02/17/2020 Adoption of Report: Amended and re-referred to the State Government Finance Division
- 02/18/2020 Adoption of Report: Amended and re-referred to the Health and Human Services Finance Division
- 02/19/2020 Adoption of Report: Amended and re-referred to the Committee on Ways and Means
- 02/20/2020 Adoption of Report: Placed on the General Register as Amended
Read for the Second Time

1.1 A bill for an act

1.2 relating to health care; establishing an emergency insulin program; establishing a

1.3 Minnesota insulin patient assistance program; requiring participation by pharmacies

1.4 and insulin manufacturers; requiring reports; appropriating money; amending

1.5 Minnesota Statutes 2019 Supplement, sections 151.06, subdivision 6; 151.252,

1.6 subdivision 1; 214.122; proposing coding for new law in Minnesota Statutes,

1.7 chapters 16B; 62Q; 62V; 151.

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

1.9 Section 1. **[16B.992] EMERGENCY INSULIN ASSISTANCE PROGRAM.**

1.10 Subdivision 1. Establishment. (a) The commissioner of administration shall implement

1.11 and administer an emergency insulin assistance program beginning July 1, 2020, for insulin

1.12 that is prescribed for self-administration on an outpatient basis.

1.13 (b) For purposes of this section, the following definitions apply:

1.14 (1) "emergency program" or "program" means the emergency insulin assistance program

1.15 established under this section;

1.16 (2) "Minnesota insulin patient assistance program" means the program established under

1.17 section 62V.12; and

1.18 (3) "navigator" has the meaning provided in section 62V.02.

1.19 Subd. 2. Contract with third-party administrator. The commissioner may contract

1.20 with a third-party administrator to provide assistance in administering the program. The

1.21 initial negotiated contract is not subject to the requirements of section 16C.06. Any contract

1.22 with a third-party administrator must:

2.1 (1) require the third-party administrator to process insulin claims and pay participating
2.2 pharmacies at a rate at least as high as the medical assistance payment rate that would apply
2.3 under section 256B.0625, subdivision 13e, for insulin that is dispensed by the participating
2.4 pharmacy to individuals under the program;

2.5 (2) prohibit the use of rebates; and

2.6 (3) state that the contract is subject to section 13.05, subdivision 11, and require that all
2.7 data be maintained as private by the third-party administrator and not be shared with a third
2.8 party without the patient's consent.

2.9 Subd. 3. **Eligibility requirements.** To be eligible for the program, an individual must
2.10 have a valid prescription for insulin and attest to:

2.11 (1) being a resident of Minnesota;

2.12 (2) not being enrolled in medical assistance or MinnesotaCare;

2.13 (3) having a tax household income that is equal to or less than 500 percent of the federal
2.14 poverty guidelines;

2.15 (4)(i) being uninsured;

2.16 (ii) having prescription drug coverage through Medicare and having incurred annual
2.17 out-of-pocket prescription drug costs that exceed \$1,000; or

2.18 (iii) having private insurance coverage with cost sharing that exceeds \$50 for a month's
2.19 supply of insulin, regardless of the amount or types of insulin needed;

2.20 (5) not being eligible to receive insulin through Indian Health Services and not being
2.21 enrolled in TRICARE or prescription drug benefits through the United States Department
2.22 of Veterans Affairs; and

2.23 (6) not having had insulin first dispensed through the program during the 12 months
2.24 preceding the date of submission of the application.

2.25 Subd. 4. **Application process.** (a) The board of directors of MNsure and the
2.26 commissioner shall jointly develop an application form to be used for this program and the
2.27 Minnesota insulin patient assistance program established under section 62V.12. The
2.28 application must:

2.29 (1) require the applicant to indicate whether insulin is being requested on an emergency
2.30 basis; and

2.31 (2) provide for the applicant's consent to any transfer of personal data.

3.1 The commissioner and the board of directors of MNsure shall make the application form
3.2 available on their websites to pharmacies and to health care practitioners who are authorized
3.3 to prescribe, administer, or dispense insulin.

3.4 (b) An applicant must submit a signed and dated application form to the MNsure board
3.5 in order to obtain insulin under the program. By signing the application, applicants are
3.6 attesting that the information contained in the application is correct and they need insulin
3.7 on an emergency basis. An application for emergency insulin may be submitted through
3.8 the MNsure website or as a paper application through a pharmacy. An individual is not
3.9 eligible to reapply for the program until 12 months have elapsed from the date insulin was
3.10 first dispensed to the individual under the program, at which time the individual must submit
3.11 a new application form.

3.12 (c) Upon receipt of a completed and signed application, the MNsure board shall verify,
3.13 if applicable, whether 12 months have elapsed from the date insulin was first dispensed
3.14 under the program to the individual. The board shall provide applicants satisfying this
3.15 criterion and new applicants with an identification number, indicating that a completed
3.16 application has been received. The information must be provided in a format that can be
3.17 downloaded by the applicant or conveyed in an electronic format.

3.18 Subd. 5. **Pharmacy participation.** (a) Each pharmacy licensed under chapter 151 that
3.19 dispenses insulin must participate in the program as a condition of doing business in this
3.20 state.

3.21 (b) A pharmacy shall dispense up to a three-month supply of insulin to individuals who
3.22 present a valid prescription, completed application, and MNsure identification number, and
3.23 who have indicated that they need insulin on an emergency basis. A pharmacy shall dispense
3.24 insulin in one-month supply increments, upon the request of an eligible individual. Upon
3.25 dispensing insulin under the program, the pharmacy must submit a claim for reimbursement
3.26 to the commissioner, in the form and manner specified by the commissioner.

3.27 (c) A pharmacy must make program applications available at each pharmacy location
3.28 and may assist applicants in applying for the program.

3.29 (d) Eligible individuals are responsible for paying a co-payment to the participating
3.30 pharmacy of \$30 for each month's supply of insulin, or a proportional co-payment for
3.31 quantities of insulin other than a month's supply, regardless of the amount or types of insulin
3.32 needed.

3.33 (e) When dispensing insulin to an eligible individual, a pharmacy must:

4.1 (1) provide the individual with the address for the website established under section
4.2 151.06, subdivision 6, paragraph (a); and

4.3 (2) provide the individual with information about the Minnesota insulin patient assistance
4.4 program established under section 62V.12.

4.5 Subd. 6. **State and federal anti-kickback provisions.** (a) The conduct of any person
4.6 or entity in participating in or administering the emergency insulin assistance program under
4.7 this section is not subject to liability under section 62J.23, subdivisions 1 and 2.

4.8 (b) No person or entity, including but not limited to any drug manufacturer, pharmacy,
4.9 pharmacist, or third-party administrator, as part of the person's or entity's participation in
4.10 or administration of the emergency insulin assistance program established under this section,
4.11 shall request or seek, or cause another to request or seek, any reimbursement or other
4.12 compensation for which payment may be made in whole or in part under a federal health
4.13 care program, as this term is defined in United States Code, title 42, section 1320a-7b(f).

4.14 Subd. 7. **Report.** By January 15, 2022, and by each January 15 thereafter, the
4.15 commissioner, in consultation with any third-party administrator under contract and the
4.16 board of directors of MNsure, shall submit a report to the chairs and ranking minority
4.17 members of the legislative committees with jurisdiction over health and human services
4.18 policy and finance on the emergency insulin assistance program for the previous fiscal year,
4.19 including:

4.20 (1) the number of individuals who received insulin under the program;

4.21 (2) the cost of the program, with a separate statement of administrative costs; and

4.22 (3) the number of individuals who reapplied for the program.

4.23 **Sec. 2. [16B.993] INSULIN ASSISTANCE ACCOUNT.**

4.24 Subdivision 1. **Establishment.** The insulin assistance account is established in the special
4.25 revenue fund in the state treasury. The fees collected by the Board of Pharmacy under section
4.26 151.252, subdivision 1, paragraph (c) shall be deposited into the account.

4.27 Subd. 2. **Use of account funds.** For fiscal year 2021 and subsequent fiscal years, money
4.28 in the insulin account is appropriated to:

4.29 (1) the commissioner of administration to reimburse pharmacies for insulin dispensed
4.30 under the emergency insulin assistance program established under section 16B.992 and for
4.31 related administrative costs, including the cost of any contract with a third-party
4.32 administrator;

5.1 (2) the board of directors of MNsure to fund administrative costs incurred by the board
5.2 in operating the Minnesota insulin patient assistance program established under section
5.3 62V.12 and related costs for the administration of the emergency insulin assistance program
5.4 established under section 16B.992; and

5.5 (3) the commissioner of human services to fund the administrative costs incurred from
5.6 the emergency insulin assistance program established under section 16B.992 and the
5.7 Minnesota insulin patient assistance program established under section 62V.12.

5.8 Subd. 3. **Transfers.** The commissioner of management and budget may transfer money
5.9 from the general fund to the insulin assistance account when the account has a projected
5.10 cash deficiency. Transfers made under this subdivision shall be included in the determination
5.11 of manufacturer's registration fees under section 151.245. The general fund shall be repaid
5.12 in full as soon as sufficient cash balances are available in the account to allow the transfer.

5.13 Sec. 3. **[62Q.491] COST-SHARING LIMIT FOR INSULIN.**

5.14 Subdivision 1. **Applicability.** This section applies to all health plans that provide coverage
5.15 for insulin.

5.16 Subd. 2. **Limit on cost sharing.** (a) All health plans included in subdivision 1 shall limit
5.17 any cost sharing for insulin to no more than \$30 for a month's supply, or proportional cost
5.18 sharing for a quantity of insulin other than a month's supply, regardless of the amount or
5.19 types of insulin needed.

5.20 (b) Nothing in this subdivision prevents a health plan company from limiting cost sharing
5.21 for insulin under a health plan to an amount lower than that specified in paragraph (a).

5.22 **EFFECTIVE DATE.** This section is effective January 1, 2021, and applies to health
5.23 plans offered, issued, or renewed on or after that date.

5.24 Sec. 4. **[62Q.678] DEPENDENT CHILD NOTICE.**

5.25 Group health plans and health plan companies that offer group or individual health plans
5.26 with dependent coverage must provide written notice to an enrollee with dependent-child
5.27 coverage and to the dependent child covered under the enrollee's plan that the dependent
5.28 child's coverage ends when the child reaches the age of 26. Notice must be sent to both the
5.29 enrollee at the enrollee's last known address and the dependent child at the dependent child's
5.30 last known address at least 90 days before the dependent child reaches the age of 26. The
5.31 notice must include the date on which coverage ends and information on accessing the
5.32 MNsure website.

6.1 Sec. 5. **[62V.12] MINNESOTA INSULIN PATIENT ASSISTANCE PROGRAM.**

6.2 Subdivision 1. **Establishment.** The MNsure board shall implement and administer the
6.3 Minnesota insulin patient assistance program beginning July 1, 2020, for insulin that is
6.4 prescribed for self-administration on an outpatient basis.

6.5 Subd. 2. **Eligibility.** (a) To be eligible for the Minnesota insulin patient assistance
6.6 program, an individual must have a valid prescription for insulin and:

6.7 (1) be a resident of Minnesota;

6.8 (2) not be enrolled in medical assistance or MinnesotaCare;

6.9 (3) have a tax household income that is equal to or less than 400 percent of the federal
6.10 poverty guidelines;

6.11 (4)(i) be uninsured;

6.12 (ii) have prescription drug coverage through Medicare and have incurred annual
6.13 out-of-pocket drug costs that exceed \$1,000; or

6.14 (iii) have private insurance coverage with cost sharing that exceeds \$50 for a month's
6.15 supply of insulin, regardless of the amount or types of insulin needed; and

6.16 (5) not be eligible to receive insulin through Indian Health Services and not be enrolled
6.17 in TRICARE or prescription drug benefits through the United States Department of Veterans
6.18 Affairs.

6.19 (b) For purposes of this section, the following definitions apply:

6.20 (1) "navigator" has the meaning provided in section 62V.02; and

6.21 (2) "program" means the Minnesota insulin patient assistance program established under
6.22 this section.

6.23 Subd. 3. **Application process; eligibility determination.** (a) The board shall make the
6.24 application form developed under section 16B.992, subdivision 4, available to pharmacies
6.25 and to health care practitioners who are authorized to prescribe, administer, or dispense
6.26 insulin. A participating pharmacy must make program applications available at each
6.27 pharmacy location. The application form must be accessible through the MNsure website.
6.28 An applicant may submit a signed and dated application form to the board through the
6.29 MNsure website, by mail or fax, or in person during normal business hours.

6.30 (b) The board shall develop and implement a process to determine if an individual is
6.31 eligible for the program. The process developed by the board may include the use of

7.1 navigators to assist the board in assessing qualifying criteria and assisting an individual in
7.2 understanding or applying for medical assistance, MinnesotaCare, the Minnesota insulin
7.3 patient assistance program, and other long-term insulin coverage options.

7.4 (c) Following receipt of a completed application submitted as specified under paragraph
7.5 (a) or transmitted as provided under section 16B.992, subdivision 4, the board must determine
7.6 eligibility for insulin coverage as provided in this subdivision. The board may require the
7.7 applicant to submit additional information to determine eligibility.

7.8 (d) The board shall first determine, using data provided by the commissioner of human
7.9 services, if the individual is enrolled in medical assistance or MinnesotaCare. If the board
7.10 determines that an individual is enrolled in one of these programs, the individual is not
7.11 eligible to participate in the Minnesota insulin patient assistance program. If the board
7.12 determines that an individual is not enrolled in medical assistance or MinnesotaCare, the
7.13 board shall refer the individual to a navigator for assistance.

7.14 (e) If an individual is referred to a navigator under paragraph (d), the navigator shall
7.15 screen the individual for eligibility for the Minnesota insulin patient assistance program
7.16 and shall notify the MNsure board for confirmation of the individual's eligibility. If the
7.17 board confirms that the individual is eligible, the board shall then:

7.18 (1) submit the individual's patient information to drug manufacturers as required by
7.19 subdivision 4; and

7.20 (2) inform the individual of eligibility and provide the individual with an eligibility
7.21 statement. The eligibility statement must identify the individual with a patient identification
7.22 number.

7.23 (f) If the individual is not found eligible under paragraphs (d) and (e), the board shall
7.24 notify the individual that the individual may qualify for an insulin coverage option specified
7.25 in this paragraph and shall provide the individual with information on how to enroll in the
7.26 coverage option or receive other assistance in obtaining affordable insulin. Insulin coverage
7.27 options include, but are not limited to:

7.28 (1) another insulin manufacturer patient assistance program;

7.29 (2) qualified health plans offered through MNsure, subject to open and special enrollment
7.30 periods;

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

8.1 (4) community health centers.

8.2 (g) The eligibility statement is valid for 12 months from the date of issuance, after which
8.3 an individual must submit a new application form to continue to participate in the program.

8.4 (h) The MNsure board shall follow the process provided in Minnesota Rules, part
8.5 7700.0105, for individuals to appeal eligibility determinations under this section.

8.6 Subd. 4. Submittal to manufacturers. (a) The board must submit the eligible patient's
8.7 identification number and other relevant information to drug manufacturers in accordance
8.8 with this section. In addition to notices and disclosures required under section 62V.06,
8.9 subdivision 6, the board must provide program applicants with notice of what information
8.10 about the applicant the board may share with drug manufacturers.

8.11 (b) A patient participating in the program may elect to receive insulin from the
8.12 manufacturer assistance program through a community pharmacy, a mail-order pharmacy,
8.13 or a health care provider designated by the patient.

8.14 Subd. 5. Manufacturer's responsibilities. (a) Each manufacturer licensed under section
8.15 151.252 that is engaged in the manufacturing of insulin that is prescribed for
8.16 self-administration on an outpatient basis must participate in the program as a condition of
8.17 doing business in this state and must operate a patient insulin assistance program that meets
8.18 the patient eligibility and other requirements of this section. Each manufacturer participating
8.19 in the program must provide the board with a fax number, mailing address, and e-mail
8.20 address for a health care practitioner to use in submitting a prescription order to the
8.21 manufacturer. For purposes of this subdivision, a prescription order includes the patient's
8.22 name, identification number, prescription, and address to where the insulin should be sent
8.23 or picked up by the patient.

8.24 (b) Upon receipt of a prescription order from a health care practitioner and the information
8.25 described in subdivision 4, the manufacturer must send a three-month supply of the product
8.26 ordered, unless a lesser amount is requested in the order, to the pharmacy or health care
8.27 provider designated by the patient at no charge to the patient, pharmacy, or health care
8.28 provider.

8.29 (c) Upon receipt of each prescription reorder for a patient, the manufacturer must send
8.30 an additional three-month supply of the product, unless a lesser amount is requested, to the
8.31 pharmacy or health care provider designated by the patient at no charge to the patient,
8.32 pharmacy, or health care provider.

9.1 (d) Each manufacturer participating in the program must annually report to the Board
9.2 of Pharmacy, in the form and manner specified by the board, information on the number of
9.3 individuals participating in the program and the quantity of insulin provided through the
9.4 program and other information necessary for the board to verify manufacturer compliance.
9.5 If a manufacturer fails to comply with the requirements of this section, the Board of Pharmacy
9.6 may assess an administrative penalty of up to \$100,000 for each month or partial month
9.7 that a manufacturer is out of compliance. This penalty is not considered a form of disciplinary
9.8 action.

9.9 (e) A manufacturer participating in the program:

9.10 (1) is subject to section 13.05, subdivision 6, as if it had entered into a contract with the
9.11 board of directors of MNsure;

9.12 (2) must maintain the privacy of all data received as part of the program; and

9.13 (3) is prohibited from selling, sharing, or disseminating data received as part of the
9.14 program, except as necessary to fulfill the requirements of the program.

9.15 Subd. 6. **Data.** (a) All data collected, created, received, maintained, or disseminated by
9.16 the board under this section related to applicants, eligible individuals, and program
9.17 participants:

9.18 (1) is classified as private data on individuals as defined in section 13.02, subdivision
9.19 12;

9.20 (2) may be shared with manufacturers participating in the program, but only with patient
9.21 consent and to the extent necessary for program operation;

9.22 (3) is subject to section 62V.06, subdivisions 6, 8, and 9; and

9.23 (4) may be retained by the board for no longer than ten years.

9.24 (b) The commissioner of human services and the board of directors of MNsure may
9.25 enter into an information-sharing agreement for purposes of determining medical assistance
9.26 and MinnesotaCare enrollment status related to operation of the patient insulin assistance
9.27 program, provided the agreement includes adequate protections with respect to the
9.28 confidentiality and integrity of the information to be shared, and complies with all applicable
9.29 state and federal laws, regulations, and rules, including the requirements in section 62V.06.

9.30 Subd. 7. **State and federal anti-kickback provisions.** (a) The conduct of any person
9.31 or entity in participating in or administering the Minnesota insulin patient assistance program
9.32 under this section is not subject to liability under section 62J.23, subdivisions 1 and 2.

10.1 (b) No person or entity, including but not limited to any drug manufacturer, pharmacy,
10.2 pharmacist, or third-party administrator, as part of the person's or entity's participation in
10.3 or administration of the Minnesota insulin patient assistance program established under this
10.4 section, shall request or seek, or cause another to request or seek, any reimbursement or
10.5 other compensation for which payment may be made in whole or in part under a federal
10.6 health care program, as this term is defined in United States Code, title 42, section
10.7 1320a-7b(f).

10.8 Subd. 8. **Report.** (a) By January 15 of each year, beginning January 15, 2021, the board
10.9 shall submit a report to the chairs and ranking minority members of the legislative committees
10.10 with jurisdiction over health and human services policy and finance on the program for the
10.11 previous calendar year. The report must provide a summary of the status of the program
10.12 and must include the number of individuals who received insulin under the program.

10.13 (b) By January 15 of each year, beginning January 15, 2021, the Board of Pharmacy
10.14 shall submit a report to the chairs and ranking minority members of the legislative committees
10.15 with jurisdiction over health and human services policy and finance on the number of
10.16 individuals participating in a drug manufacturer insulin assistance program and the quantity
10.17 of insulin products provided through the programs in the aggregate and through each drug
10.18 manufacturer insulin assistance program. The board shall also include in the report an
10.19 evaluation of the extent to which drug manufacturer insulin assistance programs comply
10.20 with the eligibility and other requirements of this section.

10.21 Sec. 6. Minnesota Statutes 2019 Supplement, section 151.06, subdivision 6, is amended
10.22 to read:

10.23 **Subd. 6. Information provision; sources of lower cost prescription drugs.** (a) The
10.24 board shall publish a page on its website that provides regularly updated information
10.25 concerning:

10.26 (1) patient assistance programs offered by drug manufacturers, including information
10.27 on how to access the programs;

10.28 (2) the emergency insulin assistance program established in section 16B.992 and the
10.29 Minnesota insulin patient assistance program established in section 62V.12, including
10.30 information on how to access each program;

10.31 (3) the prescription drug assistance program established by the Minnesota Board of
10.32 Aging under section 256.975, subdivision 9;

11.1 ~~(3)~~ (4) the websites through which individuals can access information concerning
11.2 eligibility for and enrollment in Medicare, medical assistance, MinnesotaCare, and other
11.3 government-funded programs that help pay for the cost of health care;

11.4 ~~(4)~~ (5) availability of providers that are authorized to participate under section 340b of
11.5 the federal Public Health Services Act, United States Code, title 42, section 256b;

11.6 ~~(5)~~ (6) having a discussion with the pharmacist or the consumer's health care provider
11.7 about alternatives to a prescribed drug, including a lower cost or generic drug if the drug
11.8 prescribed is too costly for the consumer; and

11.9 ~~(6)~~ (7) any other resource that the board deems useful to individuals who are attempting
11.10 to purchase prescription drugs at lower costs.

11.11 (b) The board must prepare educational materials, including brochures and posters, based
11.12 on the information it provides on its website under paragraph (a). The materials must be in
11.13 a form that can be downloaded from the board's website and used for patient education by
11.14 pharmacists and by health care practitioners who are licensed to prescribe. The board is not
11.15 required to provide printed copies of these materials.

11.16 (c) The board shall require pharmacists and pharmacies to make available to patients
11.17 information on sources of lower cost prescription drugs, including information on the
11.18 availability of the website established under paragraph (a).

11.19 **Sec. 7. [151.245] INSULIN REPORTING AND REGISTRATION FEE.**

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

11.22 (b) "Manufacturer" means a manufacturer licensed under section 151.252 engaged in
11.23 the manufacturing of insulin.

11.24 (c) "Wholesaler" means a wholesale drug distributor licensed under section 151.47 and
11.25 engaged in the wholesale drug distribution of insulin.

11.26 **Subd. 2. Reporting requirements.** (a) By March 1 of each year, beginning March 1,
11.27 2021, each manufacturer and each wholesaler must report to the Board of Pharmacy every
11.28 sale, delivery, or other distribution of insulin within or into the state that was made to any
11.29 practitioner, pharmacy, or other person who is permitted by section 151.37 to possess insulin
11.30 for outpatient dispensing to human patients during the previous calendar year. Reporting
11.31 must be in the manner and format specified by the board.

12.1 (b) By March 1 of each year, beginning March 1, 2021, each owner of a pharmacy with
12.2 at least one location within this state must report to the board any intracompany delivery
12.3 or distribution of insulin into this state, to the extent that those deliveries and distributions
12.4 are not reported to the board by a licensed wholesaler owned by, under contract to, or
12.5 otherwise operating on behalf of the owner of the pharmacy. Reporting must be in the
12.6 manner and format specified by the board for deliveries and distributions that occurred
12.7 during the previous calendar year. The report must include the name of the manufacturer
12.8 or wholesaler from which the owner of the pharmacy ultimately purchased the insulin and
12.9 the amount and date the purchase occurred.

12.10 (c) If the manufacturer, wholesaler, or pharmacy fails to provide information required
12.11 under this section on a timely basis, the board may assess an administrative penalty of up
12.12 to \$10,000 per day. This penalty is not considered a form of disciplinary action. Any penalty
12.13 assessed under this section shall be deposited in the insulin assistance account established
12.14 under section 16B.993.

12.15 **Subd. 3. Determination of manufacturer's registration fee.** (a) The board shall annually
12.16 assess manufacturers a registration fee that in aggregate equals the total cost of:

12.17 (1) the emergency insulin assistance program established under section 16B.992 for the
12.18 previous fiscal year, including any state appropriation to the commissioner of administration
12.19 to reimburse pharmacies for insulin dispensed under the program and any administrative
12.20 costs incurred by the commissioner of administration, the commissioner of human services,
12.21 and the board of directors of MNsure, or incurred by the board in collecting the fee, plus
12.22 transfers made by the commissioner of management and budget under section 16B.993,
12.23 subdivision 3, that have not been repaid to the general fund, and any outstanding liabilities
12.24 to the program; and

12.25 (2) costs incurred by the board of directors of MNsure and the commissioner of human
12.26 services in administering the Minnesota insulin patient assistance program established under
12.27 section 62V.12.

12.28 The board shall determine for each manufacturer a prorated annual insulin registration fee
12.29 that is based on the manufacturer's percentage of the total number of units reported to the
12.30 board under subdivision 2. For the first assessment, the commissioner of administration
12.31 shall estimate the cost of the programs for the first fiscal year and notify the board of the
12.32 estimated cost by May 1, 2020. The board shall determine each manufacturer's initial
12.33 registration fee based on the estimated cost, taking into account the manufacturer's percentage

13.1 of the total number of units of insulin dispensed by outpatient pharmacies and paid for by
13.2 the medical assistance program.

13.3 (b) By June 1 of each year, beginning June 1, 2020, the board shall notify each
13.4 manufacturer of the annual amount of the manufacturer's insulin registration fee to be paid
13.5 in accordance with section 151.252, subdivision 1, paragraph (c).

13.6 (c) A manufacturer may dispute the fee assessed under this section as determined by the
13.7 board no later than 30 days after the date of notification. However, the manufacturer must
13.8 still remit the registration fee required by section 151.252, subdivision 1, paragraph (c). The
13.9 dispute must be filed with the board in the manner and using the forms specified by the
13.10 board. A manufacturer must submit, with the required forms, data satisfactory to the board
13.11 that demonstrates that the fee was incorrect or otherwise unwarranted. The board must make
13.12 a decision concerning a dispute no later than 60 days after receiving the required dispute
13.13 forms. If the board determines that the manufacturer has satisfactorily demonstrated that
13.14 the original fee was incorrect, the board must:

13.15 (1)(i) adjust the manufacturer's fee;

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

13.18 (iii) refund the amount paid in error; and

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

13.21 (d) If a manufacturer fails to provide information required under subdivision 2 on a
13.22 timely basis, the board may set an annual insulin registration fee for that manufacturer,
13.23 taking into account that manufacturer's percentage of the total number of units of insulin
13.24 sold, delivered, or distributed under the medical assistance program during the previous
13.25 calendar year.

13.26 (e) If, at the end of the first fiscal year of operation of the emergency insulin assistance
13.27 program, there is any surplus from the first assessment of the annual insulin registration
13.28 fee, the surplus is appropriated to the commissioner of administration and shall be refunded
13.29 to manufacturers proportionally to their share of total fee payments.

14.1 Sec. 8. Minnesota Statutes 2019 Supplement, section 151.252, subdivision 1, is amended
14.2 to read:

14.3 Subdivision 1. **Requirements.** (a) No person shall act as a drug manufacturer without
14.4 first obtaining a license from the board and paying any applicable fee specified in section
14.5 151.065.

14.6 (b) In addition to the license required under paragraph (a), each manufacturer required
14.7 to pay the registration fee under section 151.066 must pay the fee by June 1 of each year,
14.8 beginning June 1, 2020. In the event of a change of ownership of the manufacturer, the new
14.9 owner must pay the registration fee specified under section 151.066, subdivision 3, that the
14.10 original owner would have been assessed had the original owner retained ownership. The
14.11 registration fee collected under this paragraph shall be deposited in the opiate epidemic
14.12 response account established under section 256.043.

14.13 (c) In addition to the license required under paragraph (a), a manufacturer of insulin
14.14 must pay the applicable insulin registration fee determined under section 151.245 by July
14.15 1 of each year, beginning July 1, 2020. In the event of a change of ownership of the
14.16 manufacturer, the new owner must pay the registration fee determined under section 151.245
14.17 that the original owner would have been assessed had it retained ownership. The board may
14.18 assess a late fee of ten percent per month or any portion of a month that the registration fee
14.19 is paid after the due date. The registration fee collected under this paragraph, including any
14.20 late fees, shall be deposited in the insulin assistance account established under section
14.21 16B.993.

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

14.24 ~~(d)~~ (e) No license shall be issued or renewed for a drug manufacturer unless the applicant
14.25 agrees to operate in a manner prescribed by federal and state law and according to Minnesota
14.26 Rules.

14.27 ~~(e)~~ (f) No license shall be issued or renewed for a drug manufacturer that is required to
14.28 be registered pursuant to United States Code, title 21, section 360, unless the applicant
14.29 supplies the board with proof of registration. The board may establish by rule the standards
14.30 for licensure of drug manufacturers that are not required to be registered under United States
14.31 Code, title 21, section 360.

14.32 ~~(f)~~ (g) No license shall be issued or renewed for a drug manufacturer that is required to
14.33 be licensed or registered by the state in which it is physically located unless the applicant
14.34 supplies the board with proof of licensure or registration. The board may establish, by rule,

15.1 standards for the licensure of a drug manufacturer that is not required to be licensed or
15.2 registered by the state in which it is physically located.

15.3 ~~(g)~~ (h) The board shall require a separate license for each facility located within the state
15.4 at which drug manufacturing occurs and for each facility located outside of the state at
15.5 which drugs that are shipped into the state are manufactured, except a manufacturer of
15.6 opiate-containing controlled substances shall not be required to pay the fee under section
15.7 151.065, subdivision 1, clause (16), or subdivision 3, clause (14), for more than one facility.

15.8 ~~(h)~~ (i) Prior to the issuance of an initial or renewed license for a drug manufacturing
15.9 facility, the board may require the facility to pass a current good manufacturing practices
15.10 inspection conducted by an authorized representative of the board. In the case of a drug
15.11 manufacturing facility located outside of the state, the board may require the applicant to
15.12 pay the cost of the inspection, in addition to the license fee in section 151.065, unless the
15.13 applicant furnishes the board with a report, issued by the appropriate regulatory agency of
15.14 the state in which the facility is located or by the United States Food and Drug
15.15 Administration, of an inspection that has occurred within the 24 months immediately
15.16 preceding receipt of the license application by the board. The board may deny licensure
15.17 unless the applicant submits documentation satisfactory to the board that any deficiencies
15.18 noted in an inspection report have been corrected.

15.19 Sec. 9. Minnesota Statutes 2019 Supplement, section 214.122, is amended to read:

15.20 **214.122 INFORMATION PROVISION; PHARMACEUTICAL ASSISTANCE**
15.21 **PROGRAMS.**

15.22 (a) The Board of Medical Practice and the Board of Nursing shall at least annually inform
15.23 licensees who are authorized to prescribe prescription drugs of the availability of the Board
15.24 of Pharmacy's website that contains information on resources and programs to assist patients
15.25 with the cost of prescription drugs. The boards shall provide licensees with the website
15.26 address established by the Board of Pharmacy under section 151.06, subdivision 6, and the
15.27 materials described under section 151.06, subdivision 6, paragraph (b). The boards shall
15.28 also ensure that licensees are provided with information on the emergency insulin assistance
15.29 program established under section 16B.992 and the Minnesota insulin patient assistance
15.30 program established under section 62V.12, including health care practitioners' responsibilities
15.31 under the programs and how patients can apply for the programs.

15.32 (b) Licensees must make available to patients information on sources of lower cost
15.33 prescription drugs, including information on the availability of the website established by
15.34 the Board of Pharmacy under section 151.06, subdivision 6.

16.1 Sec. 10. CITATION.

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

16.3 Sec. 11. EARLIER IMPLEMENTATION DATE FOR INSULIN ASSISTANCE
16.4 PROGRAMS.

16.5 (a) The governor may direct by executive order the commissioner of administration to
16.6 begin operating the emergency insulin assistance program before the July 1, 2020,
16.7 implementation date, and may direct by executive order the MNsure board to begin operating
16.8 the Minnesota insulin patient assistance program before the July 1, 2020, implementation
16.9 date. If the governor issues an executive order to begin the emergency insulin assistance
16.10 program or the Minnesota insulin patient assistance program, or both programs, before July
16.11 1, 2020, an amount sufficient for this purpose is appropriated to the board of directors of
16.12 MNsure, the commissioner of administration, and the commissioner of human services in
16.13 fiscal year 2020, from the insulin assistance account.

16.14 (b) If the governor does not issue executive orders under paragraph (a), the commissioner
16.15 of administration shall implement the emergency insulin assistance program beginning July
16.16 1, 2020, as required under Minnesota Statutes, section 16B.992, and the MNsure board shall
16.17 implement the Minnesota insulin patient assistance program beginning July 1, 2020, as
16.18 required under Minnesota Statutes, section 62V.12.

16.19 Sec. 12. PUBLIC AWARENESS CAMPAIGN.

16.20 The board of directors of MNsure, in consultation with the commissioner of
16.21 administration, shall conduct a public awareness campaign to create awareness of the
16.22 emergency insulin assistance program established under Minnesota Statutes, section 16B.992,
16.23 and the Minnesota insulin patient assistance program established under Minnesota Statutes,
16.24 section 62V.12. The campaign must focus on educating eligible individuals in need of
16.25 assistance in purchasing insulin of the existence of the programs and on how to apply.

16.26 Sec. 13. APPROPRIATION.

16.27 (a) \$321,000 in fiscal year 2020 is appropriated from the health care access fund to the
16.28 commissioner of administration to implement and administer the emergency insulin assistance
16.29 program established under Minnesota Statutes, section 16B.992, including the cost of any
16.30 contract with a third-party administrator. This is a onetime appropriation.

16.31 (b) \$250,000 in fiscal year 2020 is appropriated from the health care access fund to the
16.32 board of directors of MNsure for a public awareness campaign for the emergency insulin

17.1 assistance program established under Minnesota Statutes, section 16B.992 and the Minnesota
17.2 insulin patient assistance program established under Minnesota Statutes, section 62V.12.
17.3 This is a onetime appropriation.

17.4 (c) \$250,000 in fiscal year 2020 and \$250,000 in fiscal year 2021 are appropriated from
17.5 the health care access fund to the board of directors of MNsure for MNsure navigator training
17.6 and reimbursement related to the Minnesota insulin patient assistance program and the
17.7 emergency insulin assistance program. This appropriation is added to the base.

17.8 (d) \$26,000 in fiscal year 2020 is appropriated from the health care access fund to the
17.9 commissioner of human services for administrative costs related to the Minnesota insulin
17.10 patient assistance program established under Minnesota Statutes, section 62V.12. This is a
17.11 onetime appropriation.

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