MINNESOTA
BOARD OF PHARMACY

Minnesota Insulin Safety Net Program Guidance

In 2020, the Minnesota Legislature passed the Alec Smith Insulin Affordability Act, which Governor Tim Walz signed into law on April 15, 2020. (Codified primarily as Minn. Stats. §151.74). The Act creates an Insulin Safety Net Program that will aid individuals who can't afford insulin. One part of the program allows eligible individuals who are in urgent need of insulin to get a one-time, 30-day supply of insulin from their pharmacy, for a $35 co-pay. An emergency supply can normally be obtained only once in a 12-month period. However, there is an option for some individuals to receive a second 30-day supply in certain circumstances. The insulin manufacturer will reimburse the pharmacy for the insulin or send the pharmacy a replacement supply.

The second part of the program requires manufacturers to provide insulin to eligible individuals for up to one year, with the option to renew annually. The manufacturers will have to provide up to a 90-day supply of insulin for a co-pay of no more than $50. Individuals with insurance may also obtain insulin through a manufacturer's copay program, which waives all or part of the copay that the patient normally has to pay.

Pursuant to Minnesota Statutes 214.108, the Board of Pharmacy is allowed to offer guidance to licensees about the application of the statutes and rules that the Board enforces. Such guidance is not binding in any court or other adjudicatory body. Some of the comments below are recommendations that do not have the force of law and that do not have to be followed. However, some of them do state the actual requirements of the statutes. This document has been approved by the Minnesota Board of Pharmacy.

ISSUES

<u>Reimbursement for insulin dispensed vs. replacement of insulin dispensed</u>

The law requires the manufacturer to reimburse the pharmacy for its actual acquisition cost – or to send a replacement supply of insulin to the pharmacy.

- Per the statutes, if the manufacturer decides to reimburse the pharmacy, the claims must be processed using National Council for Prescription Drug Program (NCPDP) standards for *electronic* claims processing. One way the manufacturer could do that is to use a claims adjudicator. The manufacturer can't require pharmacies to submit paper claims.

- Per the statutes, pharmacies should submit a claim using their *actual acquisition cost* for the insulin dispensed.
- Pharmacies should *not* submit a dispensing fee because manufacturers are only required to reimburse pharmacies for the actual acquisition cost of the insulin.
- Based on current practices for reimbursement for claims submitted by pharmacies, it is reasonable for manufacturers to make sure that pharmacies are reimbursed within 14 days.

As an alternative, the law allows manufacturers to send to the pharmacy a replacement supply of the same insulin, in the amount dispensed. The law does not specify how quickly the manufacturer must send the replacement supply. However, the Board believes that it is reasonable for manufacturers to send a replacement supply within 14 days of receiving required documentation from the pharmacy. The required documentation can include a copy of the application submitted by the patient and a copy of the prescription that was filled.

If a manufacturer sends a replacement supply of insulin, the pharmacy would have no easy way of knowing if the patient received an urgent need supply of insulin from a different pharmacy. In that case, pharmacies should dispense the insulin if the patient has submitted a completed and signed application, attesting to the fact that they have not received an urgent need supply within the last 12 months. Manufacturers must reimburse the pharmacy or send a replacement supply, even if the patient has received an urgent need supply within the previous 12 months.

<u>Patient Identification</u>

Per the statutes, in order to receive insulin under the Minnesota Insulin Safety Net Program, patients must provide either the pharmacy or the manufacturer with identification that shows Minnesota residency. A person can use a:

- Valid Minnesota driver's license;
- Valid Minnesota identification card;
- Valid tribal identification card; or
- If the person who needs insulin is under the age of 18, the parent or legal guardian must provide proof of residency.

(Special note – for the duration of any COVID-19 Peacetime Emergency declared by the Governor, pharmacies and manufacturers may accept an expired ID card).

Retention of Records by Pharmacies

Per the statutes, a patient must submit a completed application to the pharmacy when trying to obtain insulin under the urgent need portion of the program. The pharmacy must retain a copy of the application submitted by the individual to the pharmacy for reporting and auditing purposes. Although the law doesn't specify how long the applications must be kept, it is reasonable for the Board to require pharmacies to maintain them for two years, which is the length of time that the statutes require pharmacies to maintain prescriptions.

Validity of Prescriptions

The statutes require the patient to present a valid prescription to the pharmacy – for both the urgent need and continuing need portions of the program. The statutes do not define the word "validity," which could refer to legal validity and/or clinical validity. Pharmacists are required by the statutes and rules* administered by the Board to conduct prospective drug utilization reviews, for the purpose of detecting drug-related problems and taking "appropriate steps to avoid or resolve the problem which shall, if necessary, include consultation with the prescriber." Consequently, it is reasonable for the Board interpret the term "valid prescription" to mean one that is both legally and clinically valid. If, based on the pharmacist's professional judgment, the patient might be harmed if the insulin was dispensed as prescribed, the pharmacist is not required to fill the prescription, even if it is legally valid. The pharmacist should contact the prescriber in an attempt to resolve the clinical concerns as soon as possible.

> *Minn. Stats. §151.06, subd. 1(b) states, in part: "The board shall adopt rules regarding prospective drug utilization review and patient counseling by pharmacists. A pharmacist in the exercise of the pharmacist's professional judgment, upon the presentation of a prescription by a patient or the patient's caregiver or agent, shall perform the prospective drug utilization review required by rules issued under this subdivision."
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> *Minn. Rules 680.3100 and 6800.3110 are the primary rules that the Board promulgated to fulfill the requirement of Minn. Stats. §151.06, subd. 1(b).

Manufacturer Insulin Assistance Programs Other Than Those Offered under the MnISNP

Minn. Stats. §151.74 states the following:

> "If the eligible individual has prescription drug coverage through an individual or group health plan, the manufacturer may determine that the individual's insulin needs are better

addressed through the use of the manufacturer's co-payment assistance program, in which case, the manufacturer shall inform the individual and provide the individual with the necessary coupons to submit to a pharmacy." (The patient can't be required to make a copayment that exceeds $50 per 90-day supply).

The statutes are silent about whether or not manufacturers can offer other assistance programs to Minnesota patients. In some cases, those programs offer better benefits than a person would receive under the MnISNP. Since the statutes do not specifically address other assistance programs that manufacturers might have in place, it is reasonable for the Board to interpret the statutes to allow manufacturers to offer other such programs, as long as:

- The eligibility requirements, benefits, and other relevant features of the programs are as good as or better than those of the MnISNP;
- Persons are given the choice of enrolling in the MnISNP, rather than the manufacturer's other programs*; and
- Persons enrolled in such programs are notified in advance if a program is going to be discontinued – and are allowed to enroll in the MnISNP (provided they are still eligible).

* Unless the program is a co-payment assistance program

Manufacturer Shipment of Insulin Directly to Patients

The statutes state that "a manufacturer may send the insulin as ordered directly to the individual if the manufacturer provides a mail order service option." Per Minn. Stats. §151.37, manufacturers can't dispense prescription drugs directly to patients. Only licensed practitioners and licensed pharmacists working in licensed pharmacies can dispense prescription drugs. In addition, provisions of the federal Food, Drug, and Cosmetic Act limit the prescribing and dispensing of prescription drugs to licensed professionals. Consequently, a manufacturer can only send prescription insulin directly to patients if it uses a pharmacy licensed by the Board.

Eligibility Reviews

Minn. Stats. §151.74 states the following:

> Subd. 8. **Dispute resolution.** (a) If an individual disagrees with a manufacturer's determination of eligibility under subdivision 5, the individual may contact the Board of Pharmacy to request the use of a three-person panel to review eligibility. The panel shall

be composed of three members of the board. The individual requesting the review shall submit to the board, with the request, all documents submitted by the individual to the manufacturer. The board shall provide the panel with the documents submitted by the individual. The panel shall render a decision within ten business days of receipt of all the necessary documents from the individual. The decision of the panel is final.

(b) If the panel determines that the individual is eligible, the manufacturer shall provide the individual with an eligibility statement in accordance with subdivision 5.

Per the statutes, if an individual has been determined to be not eligible, the manufacturer is required to notify the applicant and must include the reasons for denying eligibility in the notification. In order to confirm the denial and determine the manufacturer's reason for denial, it is reasonable for the Board to have the manufacturer send a copy of the denial to the Board. Along with that copy, the manufacturer can request that it be notified if a review is requested.

The following are instructions that will be provided to individuals who want to request an eligibility review:

- Fill out the Eligibility Review Form found on the Board's Web site at: https://mn.gov/boards/pharmacy/insulinsafetynetprogram/.
    - (You can also call the Board's Office at (651)201-2825 to have a copy of the form mailed to you).
- Submit the completed and signed Eligibility Review Form to the Board's Office, along with copies of all the documents that you submitted to the manufacturer and copies of all documents that the manufacturer sent to you.
    - These documents can be mailed to the Board at 2829 University Avenue SE, #530, Minneapolis, MN 55414; or
    - Faxed to the Board at (612)617-2262.
- If the Board does not receive all of the documents necessary to conduct the review, you will be asked to submit the remaining documents and given a date by which the documents must be returned.
- The Board will notify you of the decision within 10-day business days of the date on which the Board has received all necessary documents.
- The decision of the Board is final and can't be appealed.

In order for the Board to have the information necessary to conduct the review, the Eligibility Review Form will state that the following are required:

- Copies of all documents and information provided by or on behalf of the applicant to the manufacturer in support of the individual's application for enrollment in the manufacturer's continuing safety net program, including the manufacturer's completed application form and any additional information requested by the manufacturer.

- Copies of all documents and information received by the individual from the manufacturer in response to the application for enrollment in the continuing safety net program, including the manufacturer's decision regarding the individual's eligibility.

- Attestation that the documents and information submitted to the Board are accurate and complete.

- A statement explaining why the individual disagrees with or contests the manufacturer's decision regarding eligibility, including a statement identifying any information the manufacturer may assert was missing or incomplete but which the individual believes was provided.

The Board will form three panels to conduct the reviews, with each panel consisting of two pharmacist members and one public member. Each panel will be staffed by either the Executive Director, Deputy Director, or a Pharmacy Surveyor. Panel A will meet the first week each month, Panel B will meet the second week each month, and Panel C will meet the third week each month. Board members will be supplied with submitted documents in advance of the meetings. Meetings may be held virtually. Since a response must be provided within ten business days, the decisions of the panels will not have to be approved by the full Board.

Decisions will be based on the documents submitted and upon the eligibility requirements specified in the statutes. If a panel decides in favor of the manufacturer, the person requesting the review will be notified and be given an explanation of the panel's decision. If the panel decides in favor of the applicant, both parties will be notified and given an explanation for the panel's decision.