State of Wisconsin
2021 - 2022 LEGISLATURE

LRB-4377/1
EKL:wlj

2021 SENATE BILL 553

September 2, 2021 - Introduced by Senators ERPENBACH, JOHNSON, CARPENTER, AGARD, BEWLEY, LARSON, PFAFF, RINGHAND, ROYS and WIRCH, cosponsored by Representatives SUBECK, ANDERSON, CABRAL-GUEVARA, CABRERA, CONLEY, CONSIDINE, EMERSON, HEBL, HESSELBEIN, HONG, B. MEYERS, MILROY, L. MYERS, NEUBAUER, POPE, S. RODRIGUEZ, SHANKLAND, SHELTON, SINICKI, SNODGRASS, SPREITZER, STUBBS, VINING and VRUWINK. Referred to Committee on Health.

AUTHORS SUBJECT TO CHANGE

AN ACT ***to create*** 632.868 of the statutes; **relating to:** insulin safety net programs and providing a penalty.

Analysis by the Legislative Reference Bureau

This bill requires insulin manufacturers to establish a program under which qualifying Wisconsin residents who are in urgent need of insulin and are uninsured or have limited insurance coverage can be dispensed insulin at a pharmacy. Under the program, if a qualifying individual in urgent need of insulin provides a pharmacy with a form attesting that the individual meets the program's eligibility requirements, specified proof of residency, and a valid insulin prescription, the pharmacy must dispense a 30-day supply of insulin to the individual and may charge the individual a copayment of no more than $35. The pharmacy may submit an electronic payment claim for the insulin's acquisition cost to the manufacturer or agree to receive a replacement of the same insulin in the amount dispensed.

The bill also requires that insulin manufacturers establish a patient assistance program to make insulin available to any qualifying Wisconsin resident who is uninsured or has limited insurance coverage and whose income does not exceed 400 percent of the federal poverty guidelines. Under the bill, an individual must apply to participate in a manufacturer's program. If the manufacturer determines that the individual meets the program's eligibility requirements, the manufacturer issues the individual a statement of eligibility, which is valid for 12 months and may be renewed. Under the bill, if an individual with a statement of eligibility and valid insulin prescription requests insulin from a pharmacy, the pharmacy must submit an order to the manufacturer, who must then provide a 90-day supply of insulin at

no charge to the individual or pharmacy. The pharmacy may charge the individual a copayment of no more than $50. Under the bill, a manufacturer is not required to issue a statement of eligibility if the individual has prescription drug coverage through an individual or group health plan and the manufacturer determines that the individual's insulin needs are better addressed through the manufacturer's copayment assistance program. In such case, the manufacturer must provide the individual with the necessary drug coupons, and the individual may not be required to pay more than a $50 copayment for a 90–day supply of insulin.

Under the bill, if the manufacturer determines that an individual is not eligible for the patient assistance program, the individual may file an appeal with the Office of the Commissioner of Insurance. The bill directs OCI to establish procedures for deciding appeals. Under the bill, OCI must issue a decision within 10 days, and that decision is final.

The bill requires that insulin manufacturers annually report to OCI information about the number of patients served and amount of insulin dispensed under the programs and that OCI annually report to the legislature on the programs. The bill also directs OCI to conduct public outreach and develop an information sheet about the programs, conduct satisfaction surveys of individuals and pharmacies who participate in the programs, and report to the legislature on the surveys by July 1, 2024. Additionally, the bill requires that OCI develop a training program for health care navigators to assist individuals in accessing appropriate long–term insulin options and maintain a list of trained navigators.

The bill provides that a manufacturer that fails to comply with the bill's provisions may be assessed a penalty of up to $200,000 per month of noncompliance, which increases to $400,000 if the manufacturer continues to be in noncompliance after six months and to $600,000 if the manufacturer continues to be in noncompliance after one year. The bill's requirements do not apply to manufacturers with annual insulin sales revenue in Wisconsin of no more than $2,000,000 or to insulin that costs less than a specified dollar amount.

For further information see the state fiscal estimate, which will be printed as an appendix to this bill.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 632.868 of the statutes is created to read:

632.868 Insulin safety net programs. (1) DEFINITIONS. In this section:

(a) "Manufacturer" means a person engaged in the manufacturing of insulin that is self–administered on an outpatient basis.

(b) "Navigator" has the meaning given in s. 628.90 (3).

(c) "Patient assistance program" means a program established by a manufacturer under sub. (3) (a).

(d) "Pharmacy" means an entity licensed under s. 450.06 or 450.065.

(e) "Urgent need of insulin" means having less than a 7–day supply of insulin readily available for use and needing insulin in order to avoid the likelihood of suffering a significant health consequence.

(f) "Urgent need safety net program" means a program established by a manufacturer under sub. (2) (a).

(2) URGENT NEED SAFETY NET PROGRAM. (a) *Establishment of program*. No later than July 1, 2022, each manufacturer shall establish an urgent need safety net program to make insulin available in accordance with this subsection to individuals who meet the eligibility requirements under par. (b).

(b) *Eligible individual.* An individual shall be eligible to receive insulin under an urgent need safety net program if all of the following conditions are met:

1. The individual is in urgent need of insulin.

2. The individual is a resident of this state.

3. The individual is not receiving public assistance under ch. 49.

4. The individual is not enrolled in prescription drug coverage through an individual or group health plan that limits the total cost sharing amount, including copayments, deductibles, and coinsurance, that an enrollee is required to pay for a 30–day supply of insulin to no more than $75, regardless of the type or amount of insulin prescribed.

5. The individual has not received insulin under an urgent need safety net program within the previous 12 months, except as allowed under par. (d).

(c) *Provision of insulin under an urgent need safety net program*. 1. In order to receive insulin under an urgent need safety net program, an individual who meets the eligibility requirements under par. (b) shall provide a pharmacy with all of the following:

a. A completed application, on a form prescribed by the commissioner that shall include an attestation by the individual, or the individual's parent or legal guardian if the individual is under the age of 18, that the individual meets all of the eligibility requirements under par. (b).

b. A valid insulin prescription.

c. A valid Wisconsin driver's license or state identification card. If the individual is under the age of 18, the individual's parent or legal guardian shall meet this requirement.

2. Upon receipt of the information described in subd. 1. a. to c., the pharmacist shall dispense a 30–day supply of the prescribed insulin to the individual. The pharmacy shall also provide the individual with the information sheet described in sub. (8) (b) 2. and the list of navigators described in sub. (8) (c). The pharmacy may collect a copayment, not to exceed $35, from the individual to cover the pharmacy's costs of processing and dispensing the insulin. The pharmacy shall notify the health care practitioner who issued the prescription no later than 72 hours after the insulin is dispensed.

3. A pharmacy that dispenses insulin under subd. 2. may submit to the manufacturer, or the manufacturer's vendor, a claim for payment that is in accordance with the national council for prescription drug programs' standards for electronic claims processing, except that no claim may be submitted if the manufacturer agrees to send the pharmacy a replacement of the same insulin in the

amount dispensed. If the pharmacy submits an electronic claim, the manufacturer or vendor shall reimburse the pharmacy in an amount that covers the pharmacy's acquisition cost.

4. A pharmacy that dispenses insulin under subd. 2. shall retain a copy of the application form described in subd. 1. a.

(d) *Eligibility of certain individuals*. An individual who has applied for public assistance under ch. 49 but for whom a determination of eligibility has not been made or whose coverage has not become effective or an individual who has an appeal pending under sub. (3) c. 4. may access insulin under this subsection if the individual is in urgent need of insulin. To access a 30–day supply of insulin, the individual shall attest to the pharmacy that the individual is described in this paragraph and comply with par. (c) 1.

(3) PATIENT ASSISTANCE PROGRAM. (a) *Establishment of program*. No later than July 1, 2022, each manufacturer shall establish a patient assistance program to make insulin available in accordance with this subsection to individuals who meet the eligibility requirements under par. (b). Under the program, the manufacturer shall do all of the following:

1. Provide the commissioner with information regarding the program, including contact information for individuals to call for assistance in accessing the program.

2. Provide a hotline for individuals to call or access between 8 a.m. and 10 p.m. on weekdays and between 10 a.m. and 6 p.m. on Saturdays.

3. List the eligibility requirements under par. (b) on the manufacturer's Internet site.

4. Maintain the privacy of all information received from an individual applying for or participating in the program and not sell, share, or disseminate the information unless required under this section or authorized, in writing, by the individual.

(b) *Eligible individual*. An individual shall be eligible to receive insulin under a patient assistance program if all of the following conditions are met:

1. The individual is a resident of this state.

2. The individual, or the individual's parent or legal guardian if the individual is under the age of 18, has a valid Wisconsin driver's license or state identification card.

3. The individual has a valid insulin prescription.

4. The family income of the individual does not exceed 400 percent of the poverty line as defined and revised annually under 42 USC 9902 (2) for a family the size of the individual's family,

5. The individual is not receiving public assistance under ch. 49.

6. The individual is not eligible to receive health care through a federally funded program or receive prescription drug benefits through the U.S. department of veterans affairs, except that this subdivision does not apply to an individual who is enrolled in a policy under Part D of Medicare under 42 USC 1395w–101 et seq. if the individual has spent at least $1,000 on prescription drugs in the current calendar year.

7. The individual is not enrolled in prescription drug coverage through an individual or group health plan that limits the total cost sharing amount, including copayments, deductibles, and coinsurance, that an enrollee is required to pay for a

30–day supply of insulin to no more than $75, regardless of the type or amount of insulin needed.

(c) *Application for patient assistance program*. 1. An individual may apply to participate in a patient assistance program by filing an application with the manufacturer who established the program, the individual's health care practitioner if the practitioner participates in the program, or a navigator included on the list under sub. (8) (c). A health care practitioner or navigator shall immediately submit the application to the manufacturer. Upon receipt of an application, the manufacturer shall determine the individual's eligibility under par. (b) and, except as provided in subd. 2., notify the individual of the determination no later than 10 days after receipt of the application.

2. If necessary to determine the individual's eligibility under par. (b), the manufacturer may request additional information from an individual who has filed an application under subd. 1. no later than 5 days after receipt of the application. Upon receipt of the additional information, the manufacturer shall determine the individual's eligibility under par. (b) and notify the individual of the determination no later than 3 days after receipt of the requested information.

3. Except as provided in subd. 5., if the manufacturer determines under subd. 1. or 2. that the individual is eligible for the patient assistance program, the manufacturer shall provide the individual with a statement of eligibility. The statement of eligibility shall be valid for 12 months and may be renewed upon a determination by the manufacturer that the individual continues to meet the eligibility requirements of par. (b).

4. If the manufacturer determines under subd. 1. or 2. that the individual is not eligible for the patient assistance program, the manufacturer shall provide the

reason for the determination in the notification under subd. 1. or 2. The individual may appeal the determination by filing an appeal with the commissioner that shall include all of the information provided to the manufacturer under subds. 1. and 2. The commissioner shall establish procedures for deciding appeals under this subdivision. The commissioner shall issue a decision no later than 10 days after the appeal is filed, and the commissioner's decision shall be final. If the commissioner determines that the individual meets the eligibility requirements under par. (b), the manufacturer shall provide the individual with the statement of eligibility described in subd. 3.

5. In the case of an individual who has prescription drug coverage through an individual or group health plan, if the manufacturer determines under subd. 1. or 2. that the individual is eligible for the patient assistance program but also determines that the individual's insulin needs are better addressed through the use of the manufacturer's copayment assistance program rather than the patient assistance program, the manufacturer shall inform the individual of the determination and provide the individual with the necessary coupons to submit to a pharmacy. The individual may not be required to pay more than the copayment amount specified in par. (d) 2.

(d) *Provision of insulin under a patient assistance program*. 1. Upon receipt from an individual of the eligibility statement described in par. (c) 3. and a valid insulin prescription, a pharmacy shall submit an order containing the name of the insulin and daily dosage amount to the manufacturer. The pharmacy shall include with the order the pharmacy's name, shipping address, office telephone number, fax number, electronic mail address, and contact name, as well as any days or times when deliveries are not accepted by the pharmacy.

2. Upon receipt of an order meeting the requirements under subd. 1., the manufacturer shall send the pharmacy a 90–day supply of insulin, or lesser amount if requested in the order, at no charge to the individual or pharmacy. The pharmacy shall dispense the insulin to the individual associated with the order. The insulin shall be dispensed at no charge to the individual, except that the pharmacy may collect a copayment from the individual to cover the pharmacy's costs for processing and dispensing in an amount not to exceed $50 for each 90–day supply of insulin. The pharmacy may not seek reimbursement from the manufacturer or a 3rd–party payer.

3. The pharmacy may submit a reorder to the manufacturer if the individual's eligibility statement described in par. (c) 3. has not expired. The reorder shall be treated as an order for purposes of subd. 2.

4. Notwithstanding subds. 2. and 3., a manufacturer may send the insulin directly to the individual if the manufacturer provides a mail–order service option, in which case the pharmacy may not collect a copayment from the individual.

(4) EXCEPTIONS. (a) This section does not apply to a manufacturer who shows to the commissioner's satisfaction that the manufacturer's annual gross revenue from insulin sales in this state does not exceed $2,000,000.

(b) A manufacturer may not be required to make an insulin product available under sub. (2) or (3) if the wholesale acquisition cost of the insulin product does not exceed $8, as adjusted annually based on the U.S. consumer price index for all urban consumers, U.S. city average, per milliliter or the applicable national council for prescription drug programs' plan billing unit.

(5) CONFIDENTIALITY. All medical information solicited or obtained by any person under this section shall be subject to the applicable provisions of state law relating to confidentiality of medical information, including s. 610.70.

(6) REIMBURSEMENT PROHIBITION. No person, including a manufacturer, pharmacy, pharmacist, or 3rd–party administrator, as part of participating in an urgent need safety net program or patient assistance program may request or seek, or cause another person to request or seek, any reimbursement or other compensation for which payment may be made in whole or in part under a federal health care program, as defined in 42 USC 1320a–7b (f).

(7) REPORTS. (a) Annually, no later than March 1, each manufacturer shall report to the commissioner all of the following information for the previous calendar year:

1. The number of individuals who received insulin under the manufacturer's urgent need safety net program.

2. The number of individuals who sought assistance under the manufacturer's patient assistance program and the number of individuals who were determined to be ineligible under sub. (3) (c) 4.

3. The wholesale acquisition cost of the insulin provided by the manufacturer through the urgent need safety net program and patient assistance program.

(b) Annually, no later than April 1, the commissioner shall submit to the governor and the chief clerk of each house of the legislature, for distribution to the legislature under s. 13.172 (2), a report on the urgent need safety net programs and patient assistance programs that includes all of the following:

1. The information provided to the commissioner under par. (a).

2. The penalties assessed under sub. (9) during the previous calendar year, including the name of the manufacturer and amount of the penalty.

(8) ADDITIONAL RESPONSIBILITIES OF COMMISSIONER. (a) *Application form*. The commissioner shall make the application form described in sub. (2) (c) 1. a. available on the office's Internet site and shall make the form available to pharmacies and health care providers who prescribe or dispense insulin, hospital emergency departments, urgent care clinics, and community health clinics.

(b) *Public outreach*. 1. The commissioner shall conduct public outreach to create awareness of the urgent need safety net programs and patient assistance programs.

2. The commissioner shall develop and make available on the office's Internet site an information sheet that contains all of the following information:

a. A description of how to access insulin through an urgent need safety net program.

b. A description of how to access insulin through a patient assistance program.

c. Information on how to contact a navigator for assistance in accessing insulin through an urgent need safety net program or patient assistance program.

d. Information on how to contact the commissioner if a manufacturer determines that an individual is not eligible for a patient assistance program.

e. A notification that an individual may contact the commissioner for more information or assistance in accessing ongoing affordable insulin options.

(c) *Navigators*. The commissioner shall develop a training program to provide navigators with information and the resources necessary to assist individuals in accessing appropriate long–term insulin options. The commissioner shall compile a list of navigators who have completed the training program and are available to

assist individuals in accessing affordable insulin coverage options. The list shall be made available on the office's Internet site and to pharmacies and health care practitioners who dispense and prescribe insulin.

(d) *Satisfaction surveys*. 1. The commissioner shall develop and conduct a satisfaction survey of individuals who have accessed insulin through urgent need safety net programs and patient assistance programs. The survey shall ask whether the individual is still in need of a long–term solution for affordable insulin and shall include questions about the individual's satisfaction with all of the following, if applicable:

a. Accessibility to urgent–need insulin.

b. Adequacy of the information sheet and list of navigators received from the pharmacy.

c. Helpfulness of a navigator.

d. Ease of access in applying for a patient assistance program and receiving insulin from the pharmacy under the program.

2. The commissioner shall develop and conduct a satisfaction survey of pharmacies that have dispensed insulin through urgent need safety net programs and patient assistance programs. The survey shall include questions about the pharmacy's satisfaction with all of the following, if applicable:

a. Timeliness of reimbursement from manufacturers for insulin dispensed by the pharmacy under urgent need safety net programs.

b. Ease in submitting insulin orders to manufacturers.

c. Timeliness of receiving insulin orders from manufacturers.

3. The commissioner may contract with a nonprofit entity to develop and conduct the surveys under subds. 1. and 2. and to evaluate the survey results.

4. No later than July 1, 2024, the commissioner shall submit to the governor and the chief clerk of each house of the legislature, for distribution to the legislature under s. 13.172 (2), a report on the results of the surveys under subds. 1. and 2.

(9) PENALTY. A manufacturer that fails to comply with this section may be assessed a penalty of up to $200,000 per month of noncompliance, with the maximum penalty increasing to $400,000 per month if the manufacturer continues to be in noncompliance after 6 months and increasing to $600,000 per month if the manufacturer continues to be in noncompliance after one year.

(END)