# State of Misconsin 2025 - 2026 LEGISLATURE

LRBb0731/1 JPC:cdc

# ASSEMBLY AMENDMENT 11, TO ASSEMBLY SUBSTITUTE AMENDMENT 2, TO ASSEMBLY BILL 50

July 2, 2025 - Offered by Representatives Subeck, Anderson, Andraca, Arney, Bare, Billings, Brown, Clancy, Cruz, DeSanto, DeSmidt, Doyle, Emerson, Fitzgerald, Goodwin, Haywood, Hong, Hysell, J. Jacobson, Joers, Johnson, Kirsch, Madison, Mayadev, McCarville, McGuire, Miresse, Moore Omokunde, Neubauer, Palmeri, Phelps, Prado, Rivera-Wagner, Roe, Sheehan, Sinicki, Snodgrass, Spaude, Stroud, Stubbs, Taylor, Tenorio, Udell and Vining.

At the locations indicated, amend the substitute amendment as follows:

**1.** At the appropriate places, insert all of the following:

**"Section 1.** 15.07 (3) (bm) 7. of the statutes is created to read:

15.07 (3) (bm) 7. The prescription drug affordability review board shall meet at least 4 times each year.

**SECTION 2.** 15.735 of the statutes is created to read:

- **15.735 Same; attached board. (1)** There is created a prescription drug affordability review board attached to the office of the commissioner of insurance under s. 15.03. The board shall consist of the following members:
  - (a) The commissioner of insurance or his or her designee.
  - (b) Two members appointed for 4-year terms who represent the

pharmaceutical drug industry, including pharmaceutical drug manufacturers and wholesalers. At least one of the members appointed under this paragraph shall be a licensed pharmacist.

- (c) Two members appointed for 4-year terms who represent the health insurance industry, including insurers and pharmacy benefit managers.
- (d) Two members appointed for 4-year terms who represent the health care industry, including hospitals, physicians, pharmacies, and pharmacists. At least one of the members appointed under this paragraph shall be a licensed practitioner.
- (e) Two members appointed for 4-year terms who represent the interests of the public.
- (2) A member appointed under sub. (1), except for a member appointed under sub. (1) (b), may not be an employee of, a board member of, or a consultant to a drug manufacturer or trade association for drug manufacturers.
- (3) Any conflict of interest, including any financial or personal association, that has the potential to bias or has the appearance of biasing an individual's decision in matters related to the board or the conduct of the board's activities shall be considered and disclosed when appointing that individual to the board under sub. (1).

**SECTION 3.** 20.145 (1) (g) 5. of the statutes is created to read:

20.145 (1) (g) 5. All moneys received from the regulation of pharmacy benefit managers, pharmacy benefit management brokers, pharmacy benefit management

consultants, pharmacy services administration organizations, and pharmaceutical representatives.

**SECTION 4.** 601.575 of the statutes is created to read:

- 601.575 Prescription drug importation program. (1) IMPORTATION PROGRAM REQUIREMENTS. The commissioner, in consultation with persons interested in the sale and pricing of prescription drugs and appropriate officials and agencies of the federal government, shall design and implement a prescription drug importation program for the benefit of residents of this state, that generates savings for residents, and that satisfies all of the following:
- (a) The commissioner shall designate a state agency to become a licensed wholesale distributor or to contract with a licensed wholesale distributor and shall seek federal certification and approval to import prescription drugs.
- (b) The program shall comply with relevant requirements of 21 USC 384, including safety and cost savings requirements.
- (c) The program shall import prescription drugs from Canadian suppliers regulated under any appropriate Canadian or provincial laws.
- (d) The program shall have a process to sample the purity, chemical composition, and potency of imported prescription drugs.
- (e) The program shall import only those prescription drugs for which importation creates substantial savings for residents of this state and only those prescription drugs that are not brand-name drugs and that have fewer than 4 competitor prescription drugs in the United States.

- (f) The commissioner shall ensure that prescription drugs imported under the program are not distributed, dispensed, or sold outside of this state.
  - (g) The program shall ensure all of the following:
- 1. Participation by any pharmacy or health care provider in the program is voluntary.
- 2. Any pharmacy or health care provider participating in the program has the appropriate license or other credential in this state.
- 3. Any pharmacy or health care provider participating in the program charges a consumer or health plan the actual acquisition cost of the imported prescription drug that is dispensed.
- (h) The program shall ensure that a payment by a health plan or health insurance policy for a prescription drug imported under the program reimburses no more than the actual acquisition cost of the imported prescription drug that is dispensed.
- (i) The program shall ensure that any health plan or health insurance policy participating in the program does all of the following:
- 1. Maintains a formulary and claims payment system with current information on prescription drugs imported under the program.
- 2. Bases cost-sharing amounts for participants or insureds under the plan or policy on no more than the actual acquisition cost of the prescription drug imported under the program that is dispensed to the participant or insured.
  - 3. Demonstrates to the commissioner or a state agency designated by the

commissioner how premiums under the plan or policy are affected by savings on prescription drugs imported under the program.

- (j) Any wholesale distributor importing prescription drugs under the program shall limit its profit margin to the amount established by the commissioner or a state agency designated by the commissioner.
- (k) The program may not import any generic prescription drug that would violate federal patent laws on branded products in the United States.
- (L) The program shall comply with tracking and tracing requirements of 21 USC 360eee and 360eee-1, to the extent practical and feasible, before the prescription drug to be imported comes into the possession of this state's wholesale distributor and fully after the prescription drug to be imported is in the possession of this state's wholesale distributor.
- (m) The program shall establish a fee or other mechanism to finance the program that does not jeopardize significant savings to residents of this state.
  - (n) The program shall have an audit function that ensures all of the following:
- 1. The commissioner has a sound methodology to determine the most costeffective prescription drugs to include in the program.
- 2. The commissioner has a process in place to select Canadian suppliers that are high quality, high performing, and in full compliance with Canadian laws.
- 3. Prescription drugs imported under the program are pure, unadulterated, potent, and safe.
  - 4. The program is complying with the requirements of this subsection.

- 5. The program is adequately financed to support administrative functions of the program while generating significant cost savings to residents of this state.
- 6. The program does not put residents of this state at a higher risk than if the program did not exist.
- 7. The program provides and is projected to continue to provide substantial cost savings to residents of this state.
- (2) ANTICOMPETITIVE BEHAVIOR. The commissioner, in consultation with the attorney general, shall identify the potential for and monitor anticompetitive behavior in industries affected by a prescription drug importation program.
- (3) APPROVAL OF PROGRAM DESIGN; CERTIFICATION. No later than the first day of the 7th month beginning after the effective date of this subsection .... [LRB inserts date], the commissioner shall submit to the joint committee on finance a report that includes the design of the prescription drug importation program in accordance with this section. The commissioner may not submit the proposed program to the federal department of health and human services unless the joint committee on finance approves the proposed program. Within 14 days of the date of approval by the joint committee on finance of the proposed program, the commissioner shall submit to the federal department of health and human services a request for certification of the approved program.
- (4) IMPLEMENTATION OF CERTIFIED PROGRAM. After the federal department of health and human services certifies the prescription drug importation program submitted under sub. (3), the commissioner shall begin implementation of the program, and the program shall be fully operational by 180 days after the date of

certification by the federal department of health and human services. The commissioner shall do all of the following to implement the program to the extent the action is in accordance with other state laws and the certification by the federal department of health and human services:

- (a) Become a licensed wholesale distributor, designate another state agency to become a licensed wholesale distributor, or contract with a licensed wholesale distributor.
- (b) Contract with one or more Canadian suppliers that meet the criteria in sub. (1) (c) and (n).
- (c) Create an outreach and marketing plan to communicate with and provide information to health plans and health insurance policies, employers, pharmacies, health care providers, and residents of this state on participating in the program.
- (d) Develop and implement a registration process for health plans and health insurance policies, pharmacies, and health care providers interested in participating in the program.
- (e) Create a publicly accessible source for listing prices of prescription drugs imported under the program.
- (f) Create, publicize, and implement a method of communication to promptly answer questions from and address the needs of persons affected by the implementation of the program before the program is fully operational.
- (g) Establish the audit functions under sub. (1) (n) with a timeline to complete each audit function every 2 years.

- (h) Conduct any other activities determined by the commissioner to be important to successful implementation of the program.
- (5) REPORT. By January 1 and July 1 of each year, the commissioner shall submit to the joint committee on finance a report including all of the following:
- (a) A list of prescription drugs included in the prescription drug importation program under this section.
- (b) The number of pharmacies, health care providers, and health plans and health insurance policies participating in the prescription drug importation program under this section.
- (c) The estimated amount of savings to residents of this state, health plans and health insurance policies, and employers resulting from the implementation of the prescription drug importation program under this section reported from the date of the previous report under this subsection and from the date the program was fully operational.
- (d) Findings of any audit functions under sub. (1) (n) completed since the date of the previous report under this subsection.
- **(6)** RULEMAKING. The commissioner may promulgate any rules necessary to implement this section.
- **SECTION 5.** Subchapter VI (title) of chapter 601 [precedes 601.78] of the statutes is created to read:

### CHAPTER 601

SUBCHAPTER VI

PRESCRIPTION DRUG

### AFFORDABILITY REVIEW BOARD

**SECTION 6.** 601.78 of the statutes is created to read:

### **601.78 Definitions.** In this subchapter:

- (1) "Biologic" means a drug that is produced or distributed in accordance with a biologics license application approved under 21 CFR 601.20.
- (2) "Biosimilar" means a drug that is produced or distributed in accordance with a biologics license application approved under 42 USC 262 (k) (3).
- (3) "Board" means the prescription drug affordability review board established under s. 15.735 (1).
- (4) "Brand name drug" means a drug that is produced or distributed in accordance with an original new drug application approved under 21 USC 355 (c), other than an authorized generic drug, as defined in 42 CFR 447.502.
- (5) "Financial benefit" includes an honorarium, fee, stock, the value of the stock holdings of a member of the board or any immediate family member of the member of the board, and any direct financial benefit deriving from the finding of a review conducted under s. 601.79.
  - (6) "Generic drug" means any of the following:
- (a) A retail drug that is marketed or distributed in accordance with an abbreviated new drug application approved under 21 USC 355 (j).
  - (b) An authorized generic drug, as defined in 42 CFR 447.502.
- (c) A drug that entered the market prior to 1962 and was not originally marketed under a new drug application.
  - (7) "Immediate family member" means a spouse, grandparent, parent,

sibling, child, stepchild, or grandchild or the spouse of a grandparent, parent, sibling, child, stepchild, or grandchild.

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- (8) "Manufacturer" means an entity that does all of the following:
- (a) Engages in the manufacture of a prescription drug product or enters into a lease with another entity to market and distribute a prescription drug product under the entity's own name.
- (b) Sets or changes the wholesale acquisition cost of the prescription drug product described in par. (a).
  - (9) "Pharmacy benefit manager" has the meaning given in s. 632.865 (1) (c).
- (10) "Prescription drug product" means a brand name drug, a generic drug, a biologic, or a biosimilar.

**SECTION 7.** 601.785 of the statutes is created to read:

- 601.785 Prescription drug affordability review board. (1) MISSION. The purpose of the board is to protect state residents, the state, local governments, health plans, health care providers, pharmacies licensed in this state, and other stakeholders of the health care system in this state from the high costs of prescription drug products.
  - (2) POWERS AND DUTIES. (a) The board shall do all of the following:
- 1. Meet in open session at least 4 times per year to review prescription drug product pricing information in the manner described in subd. 2., except that the chairperson may cancel or postpone a meeting if there is no business to transact.
- 2. To the extent practicable, access and assess pricing information for prescription drug products by doing all of the following:

- a. Accessing and assessing information from other states by entering into memoranda of understanding with other states to which manufacturers report pricing information.
  - b. Assessing spending for specific prescription drug products in this state.
  - c. Accessing other available pricing information.
  - (b) The board may do any of the following:
  - 1. Promulgate rules for the administration of this subchapter.
- 2. Enter into a contract with an independent 3rd party for any service necessary to carry out the powers and duties of the board. Unless written permission is granted by the board, any person with whom the board contracts may not release, publish, or otherwise use any information to which the person has access under the contract.
- (c) The board shall establish and maintain a website to provide public notices and make meeting materials available under sub. (3) (a) and to disclose conflicts of interest under sub. (4) (d).
- (3) MEETING REQUIREMENTS. (a) Pursuant to s. 19.84, the board shall provide public notice of each board meeting at least 2 weeks prior to the meeting and shall make the materials for each meeting publicly available at least one week prior to the meeting.
- (b) Notwithstanding s. 19.84 (2), the board shall provide an opportunity for public comment at each open meeting and shall provide the public with the opportunity to provide written comments on pending decisions of the board.
  - (c) Notwithstanding subch. V of ch. 19, any portion of a meeting of the board

concerning proprietary data and information shall be conducted in closed session and shall in all respects remain confidential.

- (d) The board may allow expert testimony at any meeting, including when the board meets in closed session.
- (4) CONFLICTS OF INTEREST. (a) A member of the board shall recuse himself or herself from a decision by the board relating to a prescription drug product if the member or an immediate family member of the member has received or could receive any of the following:
- 1. A direct financial benefit deriving from a determination, or a finding of a study or review, by the board relating to the prescription drug product.
- 2. A financial benefit in excess of \$5,000 in a calendar year from any person who owns, manufactures, or provides a prescription drug product to be studied or reviewed by the board.
- (b) A conflict of interest under this subsection shall be disclosed by the board when hiring board staff, by the appointing authority when appointing members to the board, and by the board when a member of the board is recused from any decision relating to a review of a prescription drug product.
- (c) A conflict of interest under this subsection shall be disclosed no later than 5 days after the conflict is identified, except that, if the conflict is identified within 5 days of an open meeting of the board, the conflict shall be disclosed prior to the meeting.
- (d) The board shall disclose a conflict of interest under this subsection on the board's website unless the chairperson of the board recuses the member from a final

decision relating to a review of the prescription drug product. The disclosure shall include the type, nature, and magnitude of the interests of the member involved.

(e) A member of the board or a 3rd-party contractor may not accept any gift or donation of services or property that indicates a potential conflict of interest or has the appearance of biasing the work of the board.

**SECTION 8.** 601.79 of the statutes is created to read:

- 601.79 Drug cost affordability review. (1) IDENTIFICATION OF DRUGS.

  The board shall identify prescription drug products that are any of the following:
- (a) A brand name drug or biologic that, as adjusted annually to reflect adjustments to the U.S. consumer price index for all urban consumers, U.S. city average, as determined by the U.S. department of labor, has a launch wholesale acquisition cost of at least \$30,000 per year or course of treatment.
- (b) A brand name drug or biologic that, as adjusted annually to reflect adjustments to the U.S. consumer price index for all urban consumers, U.S. city average, as determined by the U.S. department of labor, has a wholesale acquisition cost that has increased by at least \$3,000 during a 12-month period.
- (c) A biosimilar that has a launch wholesale acquisition cost that is not at least 15 percent lower than the referenced brand biologic at the time the biosimilar is launched.
- (d) A generic drug that has a wholesale acquisition cost, as adjusted annually to reflect adjustments to the U.S. consumer price index for all urban consumers, U.S. city average, as determined by the U.S. department of labor, that meets all of the following conditions:

- 1. Is at least \$100 for a supply lasting a patient for a period of 30 consecutive days based on the recommended dosage approved for labeling by the federal food and drug administration, a supply lasting a patient for a period of fewer than 30 days based on the recommended dosage approved for labeling by the federal food and drug administration, or one unit of the drug if the labeling approved by the federal food and drug administration does not recommend a finite dosage.
- 2. Increased by at least 200 percent during the preceding 12-month period, as determined by the difference between the resulting wholesale acquisition cost and the average of the wholesale acquisition cost reported over the preceding 12 months.
- (e) Other prescription drug products, including drugs to address public health emergencies, that may create affordability challenges for the health care system and patients in this state.
- (2) AFFORDABILITY REVIEW. (a) After identifying prescription drug products under sub. (1), the board shall determine whether to conduct an affordability review for each identified prescription drug product by seeking stakeholder input about the prescription drug product and considering the average patient cost share of the prescription drug product.
- (b) The information used to conduct an affordability review under par. (a) may include any document and research related to the manufacturer's selection of the introductory price or price increase of the prescription drug product, including life cycle management, net average price in this state, market competition and context,

projected revenue, and the estimated value or cost-effectiveness of the prescription drug product.

- (c) The failure of a manufacturer to provide the board with information for an affordability review under par. (b) does not affect the authority of the board to conduct the review.
- (3) AFFORDABILITY CHALLENGE. When conducting an affordability review of a prescription drug product under sub. (2), the board shall determine whether use of the prescription drug product that is fully consistent with the labeling approved by the federal food and drug administration or standard medical practice has led or will lead to an affordability challenge for the health care system in this state, including high out-of-pocket costs for patients. To the extent practicable, in determining whether a prescription drug product has led or will lead to an affordability challenge, the board shall consider all of the following factors:
- (a) The wholesale acquisition cost for the prescription drug product sold in this state.
- (b) The average monetary price concession, discount, or rebate the manufacturer provides, or is expected to provide, to health plans in this state as reported by manufacturers and health plans, expressed as a percentage of the wholesale acquisition cost for the prescription drug product under review.
- (c) The total amount of the price concessions, discounts, and rebates the manufacturer provides to each pharmacy benefit manager for the prescription drug product under review, as reported by the manufacturer and pharmacy benefit manager and expressed as a percentage of the wholesale acquisition cost.

- (d) The price at which therapeutic alternatives to the prescription drug product have been sold in this state.
- (e) The average monetary concession, discount, or rebate the manufacturer provides or is expected to provide to health plan payors and pharmacy benefit managers in this state for therapeutic alternatives to the prescription drug product.
- (f) The costs to health plans based on patient access consistent with labeled indications by the federal food and drug administration and recognized standard medical practice.
- (g) The impact on patient access resulting from the cost of the prescription drug product relative to insurance benefit design.
- (h) The current or expected dollar value of drug-specific patient access programs that are supported by the manufacturer.
- (i) The relative financial impacts to health, medical, or social services costs that can be quantified and compared to baseline effects of existing therapeutic alternatives to the prescription drug product.
- (j) The average patient copay or other cost sharing for the prescription drug product in this state.
  - (k) Any information a manufacturer chooses to provide.
  - (L) Any other factors as determined by the board by rule.
- (4) UPPER PAYMENT LIMIT. (a) If the board determines under sub. (3) that use of a prescription drug product has led or will lead to an affordability challenge, the board shall establish an upper payment limit for the prescription drug product after considering all of the following:

- 1. The cost of administering the drug.
- 2. The cost of delivering the drug to consumers.
- 3. Other relevant administrative costs related to the drug.
- (b) For a prescription drug product identified in sub. (1) (b) or (d) 2., the board shall solicit information from the manufacturer regarding the price increase. To the extent that the price increase is not a result of the need for increased manufacturing capacity or other effort to improve patient access during a public health emergency, the board shall establish an upper payment limit under par. (a) that is equal to the cost to consumers prior to the price increase.
- (c) 1. The upper payment limit established under this subsection shall apply to all purchases and payor reimbursements of the prescription drug product dispensed or administered to individuals in this state in person, by mail, or by other means.
- 2. Notwithstanding subd. 1., while state-sponsored and state-regulated health plans and health programs shall limit drug reimbursements and drug payment to no more than the upper payment limit established under this subsection, a plan subject to the Employee Retirement Income Security Act of 1974 or Part D of Medicare under 42 USC 1395w-101 et seq. may choose to reimburse more than the upper payment limit. A provider who dispenses and administers a prescription drug product in this state to an individual in this state may not bill a payor more than the upper payment limit to the patient regardless of whether a plan subject to the Employee Retirement Income Security Act of 1974 or Part D of

Medicare under 42 USC 1395w-101 et seq. chooses to reimburse the provider above the upper payment limit.

- (5) PUBLIC INSPECTION. Information submitted to the board under this section shall be open to public inspection only as provided under ss. 19.31 to 19.39.
- (6) NO PROHIBITION ON MARKETING. Nothing in this section may be construed to prevent a manufacturer from marketing a prescription drug product approved by the federal food and drug administration while the prescription drug product is under review by the board.
- (7) APPEALS. A person aggrieved by a decision of the board may request an appeal of the decision no later than 30 days after the board makes the determination. The board shall hear the appeal and make a final decision no later than 60 days after the appeal is requested. A person aggrieved by a final decision of the board may petition for judicial review in a court of competent jurisdiction.

**SECTION 9.** 609.83 of the statutes is amended to read:

**609.83** Coverage of drugs and devices. Limited service health organizations, preferred provider plans, and defined network plans are subject to ss. 632.853, 632.861, and 632.895 (6) (b), (16t), and (16v).

**SECTION 10.** 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, 2026, 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, 2026, 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 patient assistance program, the manufacturer shall do all of the following:
  - 1. Provide the commissioner with information regarding the patient

assistance program, including contact information for individuals to call for assistance in accessing the patient assistance 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 website.
- 4. Maintain the privacy of all information received from an individual applying for or participating in the patient assistance 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 that established the patient assistance program, the individual's health care practitioner if the practitioner participates in the patient assistance 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 under 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, email 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 that 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 website 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 website 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 that 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 website 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 patient assistance 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, 2028, 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 violates this section may be required to forfeit not more than \$200,000 per month of violation, with the maximum forfeiture increasing to \$400,000 per month if the manufacturer continues to be in violation after 6 months and increasing to \$600,000 per month if the manufacturer continues to be in violation after one year.

**SECTION 11.** 632.895 (6) (title) of the statutes is amended to read:

632.895 (6) (title) Equipment and supplies for treatment of diabetes; <u>Insulin</u>.

**SECTION 12.** 632.895 (6) of the statutes is renumbered 632.895 (6) (a) and amended to read:

632.895 (6) (a) Every disability insurance policy which that provides coverage of expenses incurred for treatment of diabetes shall provide coverage for expenses incurred by the installation and use of an insulin infusion pump, coverage for all other equipment and supplies, including insulin or any other prescription medication, used in the treatment of diabetes, and coverage of diabetic self-management education programs. Coverage Except as provided in par. (b), coverage required under this subsection shall be subject to the same exclusions, limitations, deductibles, and coinsurance provisions of the policy as other covered expenses, except that insulin infusion pump coverage may be limited to the purchase of one pump per year and the insurer may require the insured to use a pump for 30 days before purchase.

**SECTION 13.** 632.895 (6) (b) of the statutes is created to read:

632.895 **(6)** (b) 1. In this paragraph:

- a. "Cost sharing" means the total of any deductible, copayment, or coinsurance amounts imposed on a person covered under a disability insurance policy or self-insured health plan.
  - b. "Self-insured health plan" has the meaning given in s. 632.85 (1) (c).
- 2. Every disability insurance policy and self-insured health plan that covers insulin and imposes cost sharing on prescription drugs may not impose cost sharing on insulin in an amount that exceeds \$35 for a one-month supply of insulin.
- 3. Nothing in this paragraph prohibits a disability insurance policy or self-insured health plan from imposing cost sharing on insulin in an amount less than the amount specified under subd. 2. Nothing in this paragraph requires a disability insurance policy or self-insured health plan to impose any cost sharing on insulin.

## SECTION 9123. Nonstatutory provisions; Insurance.

- (1) STAGGERED TERMS FOR PRESCRIPTION DRUG AFFORDABILITY REVIEW BOARD. Notwithstanding the length of terms specified for the members of the prescription drug affordability review board under s. 15.735 (1) (b) to (e), 2 of the initial members shall be appointed for terms expiring on May 1, 2027; 2 of the initial members shall be appointed for terms expiring on May 1, 2028; 2 of the initial members shall be appointed for terms expiring on May 1, 2029; and 2 of the initial members shall be appointed for terms expiring on May 1, 2030.
- (2) PRESCRIPTION DRUG IMPORTATION PROGRAM. The commissioner of insurance shall submit the first report required under s. 601.575 (5) by the next January 1 or July 1, whichever is earliest, that is at least 180 days after the date the prescription drug importation program is fully operational under s. 601.575 (4).

The commissioner of insurance shall include in the first 3 reports submitted under s. 601.575 (5) information on the implementation of the audit functions under s. 601.575 (1) (n).

(3) PRESCRIPTION DRUG PURCHASING ENTITY. During the 2025-27 fiscal biennium, the office of the commissioner of insurance shall conduct a study on the viability of creating or implementing a state prescription drug purchasing entity.

### SECTION 9223. Fiscal changes; Insurance.

(1) OFFICE OF PRESCRIPTION DRUG AFFORDABILITY. In the schedule under s. 20.005 (3) for the appropriation to the office of the commissioner of insurance under s. 20.145 (1) (g), the dollar amount for fiscal year 2025-26 is increased by \$1,957,300 to provide \$500,000 in onetime implementation costs for establishing an office of prescription drug affordability in the office of the commissioner of insurance and \$1,457,300 to authorize 16.0 PR positions within the office of prescription drug affordability, including 5.0 insurance examiners, 4.0 policy initiatives advisors, 2.0 attorneys, 1.0 insurance program manager, 2.0 insurance administrators, and 2.0 operations program associates. In the schedule under s. 20.005 (3) for the appropriation to the office of the commissioner of insurance under s. 20.145 (1) (g), the dollar amount for fiscal year 2026-27 is increased by \$1,871,100 to fund the positions authorized under this subsection.

## SECTION 9423. Effective dates; Insurance.

(1) PRESCRIPTION DRUG AFFORDABILITY REVIEW BOARD. The treatment of ss. 15.07 (3) (bm) 7., 15.735, 601.78, 601.785, and 601.79 and subch. VI (title) of ch. 601 and SECTION 9123 (1) of this act take effect on the first day of the 7th month beginning after publication.

(2) COST-SHARING CAP ON INSULIN. The treatment of ss. 609.83 and 632.895 (6) (title), the renumbering and amendment of s. 632.895 (6), and the creation of s. 632.895 (6) (b) take effect on the first day of the 4th month beginning after publication.".

(END)