

State of Misconsin 2025 - 2026 LEGISLATURE

# 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.

## \*\*\*AUTHORS SUBJECT TO CHANGE\*\*\*

1	At the locations indicated, amend the substitute amendment as follows:
2	<b>1.</b> At the appropriate places, insert all of the following:
3	"SECTION 1. 15.07 (3) (bm) 7. of the statutes is created to read:
4	15.07 (3) (bm) 7. The prescription drug affordability review board shall meet
5	at least 4 times each year.
6	<b>SECTION 2.</b> 15.735 of the statutes is created to read:
7	15.735 Same; attached board. (1) There is created a prescription drug
8	affordability review board attached to the office of the commissioner of insurance
9	under s. 15.03. The board shall consist of the following members:
10	(a) The commissioner of insurance or his or her designee.
11	(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.

- 4 (c) Two members appointed for 4-year terms who represent the health
  5 insurance industry, including insurers and pharmacy benefit managers.
- 6 (d) Two members appointed for 4-year terms who represent the health care
  7 industry, including hospitals, physicians, pharmacies, and pharmacists. At least
  8 one of the members appointed under this paragraph shall be a licensed
  9 practitioner.
- 10 (e) Two members appointed for 4-year terms who represent the interests of11 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).

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

21 20.145 (1) (g) 5. All moneys received from the regulation of pharmacy benefit
 22 managers, pharmacy benefit management brokers, pharmacy benefit management

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consultants, pharmacy services administration organizations, and pharmaceutical
 representatives.

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**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.

13 (b) The program shall comply with relevant requirements of 21 USC 384,
14 including safety and cost savings requirements.

15 (c) The program shall import prescription drugs from Canadian suppliers
16 regulated under any appropriate Canadian or provincial laws.

17 (d) The program shall have a process to sample the purity, chemical18 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.

1	(f) The commissioner shall ensure that prescription drugs imported under the
2	program are not distributed, dispensed, or sold outside of this state.
3	(g) The program shall ensure all of the following:
4	1. Participation by any pharmacy or health care provider in the program is
5	voluntary.
6	2. Any pharmacy or health care provider participating in the program has the
7	appropriate license or other credential in this state.
8	3. Any pharmacy or health care provider participating in the program charges
9	a consumer or health plan the actual acquisition cost of the imported prescription
10	drug that is dispensed.
11	(h) The program shall ensure that a payment by a health plan or health
12	insurance policy for a prescription drug imported under the program reimburses no
13	more than the actual acquisition cost of the imported prescription drug that is
14	dispensed.
15	(i) The program shall ensure that any health plan or health insurance policy
16	participating in the program does all of the following:
17	1. Maintains a formulary and claims payment system with current
18	information on prescription drugs imported under the program.
19	2. Bases cost-sharing amounts for participants or insureds under the plan or
20	policy on no more than the actual acquisition cost of the prescription drug imported
21	under the program that is dispensed to the participant or insured.
22	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.

3 (j) Any wholesale distributor importing prescription drugs under the program
4 shall limit its profit margin to the amount established by the commissioner or a
5 state agency designated by the commissioner.

6 (k) The program may not import any generic prescription drug that would
7 violate federal patent laws on branded products in the United States.

8 (L) The program shall comply with tracking and tracing requirements of 21 9 USC 360eee and 360eee-1, to the extent practical and feasible, before the 10 prescription drug to be imported comes into the possession of this state's wholesale 11 distributor and fully after the prescription drug to be imported is in the possession 12 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.

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(n) The program shall have an audit function that ensures all of the following:

16 1. The commissioner has a sound methodology to determine the most cost effective prescription drugs to include in the program.

18 2. The commissioner has a process in place to select Canadian suppliers that19 are high quality, high performing, and in full compliance with Canadian laws.

20 3. Prescription drugs imported under the program are pure, unadulterated,
21 potent, and safe.

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4. The program is complying with the requirements of this subsection.

1 5. The program is adequately financed to support administrative functions of  $\mathbf{2}$ the program while generating significant cost savings to residents of this state. 3 6. The program does not put residents of this state at a higher risk than if the 4 program did not exist.  $\mathbf{5}$ 7. The program provides and is projected to continue to provide substantial 6 cost savings to residents of this state. 7 (2) ANTICOMPETITIVE BEHAVIOR. The commissioner, in consultation with the 8 attorney general, shall identify the potential for and monitor anticompetitive 9 behavior in industries affected by a prescription drug importation program. 10 (3) APPROVAL OF PROGRAM DESIGN; CERTIFICATION. No later than the first day 11 of the 7th month beginning after the effective date of this subsection .... [LRB 12inserts date], the commissioner shall submit to the joint committee on finance a 13report that includes the design of the prescription drug importation program in 14 accordance with this section. The commissioner may not submit the proposed program to the federal department of health and human services unless the joint 1516 committee on finance approves the proposed program. Within 14 days of the date of 17approval by the joint committee on finance of the proposed program, the 18 commissioner shall submit to the federal department of health and human services 19 a request for certification of the approved program. 20 (4) IMPLEMENTATION OF CERTIFIED PROGRAM. After the federal department of

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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

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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:

5 (a) Become a licensed wholesale distributor, designate another state agency to
6 become a licensed wholesale distributor, or contract with a licensed wholesale
7 distributor.

8 (b) Contract with one or more Canadian suppliers that meet the criteria in
9 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.

13 (d) Develop and implement a registration process for health plans and health
14 insurance policies, pharmacies, and health care providers interested in
15 participating in the program.

16 (e) Create a publicly accessible source for listing prices of prescription drugs
17 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.

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

1	AFFORDABILITY REVIEW BOARD
2	<b>SECTION 6.</b> 601.78 of the statutes is created to read:
3	601.78 Definitions. In this subchapter:
4	(1) "Biologic" means a drug that is produced or distributed in accordance with
5	a biologics license application approved under 21 CFR 601.20.
6	(2) "Biosimilar" means a drug that is produced or distributed in accordance
7	with a biologics license application approved under 42 USC 262 (k) (3).
8	(3) "Board" means the prescription drug affordability review board
9	established under s. 15.735 (1).
10	(4) "Brand name drug" means a drug that is produced or distributed in
11	accordance with an original new drug application approved under 21 USC 355 (c),
12	other than an authorized generic drug, as defined in 42 CFR 447.502.
13	(5) "Financial benefit" includes an honorarium, fee, stock, the value of the
14	stock holdings of a member of the board or any immediate family member of the
15	member of the board, and any direct financial benefit deriving from the finding of a
16	review conducted under s. 601.79.
17	(6) "Generic drug" means any of the following:
18	(a) A retail drug that is marketed or distributed in accordance with an
19	abbreviated new drug application approved under 21 USC 355 (j).
20	(b) An authorized generic drug, as defined in 42 CFR 447.502.
21	(c) A drug that entered the market prior to 1962 and was not originally
22	marketed under a new drug application.
23	(7) "Immediate family member" means a spouse, grandparent, parent,

1	sibling, child, stepchild, or grandchild or the spouse of a grandparent, parent,
2	sibling, child, stepchild, or grandchild.
3	(8) "Manufacturer" means an entity that does all of the following:
4	(a) Engages in the manufacture of a prescription drug product or enters into
5	a lease with another entity to market and distribute a prescription drug product
6	under the entity's own name.
7	(b) Sets or changes the wholesale acquisition cost of the prescription drug
8	product described in par. (a).
9	(9) "Pharmacy benefit manager" has the meaning given in s. 632.865 (1) (c).
10	(10) "Prescription drug product" means a brand name drug, a generic drug, a
11	biologic, or a biosimilar.
10	<b>SECTION 7.</b> 601.785 of the statutes is created to read:
12	SECTION 7. 001.705 of the statutes is created to read.
$\frac{12}{13}$	<b>601.785 Prescription drug affordability review board.</b> (1) MISSION.
13	601.785 Prescription drug affordability review board. (1) MISSION.
$13\\14$	<b>601.785 Prescription drug affordability review board. (1)</b> MISSION. The purpose of the board is to protect state residents, the state, local governments,
13 14 15	<b>601.785 Prescription drug affordability review board. (1)</b> 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
13 14 15 16	<b>601.785 Prescription drug affordability review board.</b> (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
13 14 15 16 17	<b>601.785 Prescription drug affordability review board.</b> (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.
13 14 15 16 17 18	<ul> <li>601.785 Prescription drug affordability review board. (1) MISSION.</li> <li>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.</li> <li>(2) POWERS AND DUTIES. (a) The board shall do all of the following:</li> </ul>
13 14 15 16 17 18 19	<ul> <li>601.785 Prescription drug affordability review board. (1) MISSION.</li> <li>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.</li> <li>(2) POWERS AND DUTIES. (a) The board shall do all of the following:</li> <li>1. Meet in open session at least 4 times per year to review prescription drug</li> </ul>
13 14 15 16 17 18 19 20	<ul> <li>601.785 Prescription drug affordability review board. (1) MISSION.</li> <li>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.</li> <li>(2) POWERS AND DUTIES. (a) The board shall do all of the following: <ol> <li>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</li> </ol> </li> </ul>
<ol> <li>13</li> <li>14</li> <li>15</li> <li>16</li> <li>17</li> <li>18</li> <li>19</li> <li>20</li> <li>21</li> </ol>	<ul> <li>601.785 Prescription drug affordability review board. (1) MISSION.</li> <li>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.</li> <li>(2) POWERS AND DUTIES. (a) The board shall do all of the following:</li> <li>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.</li> </ul>

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

(c) Notwithstanding subch. V of ch. 19, any portion of a meeting of the board

1 concerning proprietary data and information shall be conducted in closed session  $\mathbf{2}$ and shall in all respects remain confidential. 3 (d) The board may allow expert testimony at any meeting, including when the 4 board meets in closed session.  $\mathbf{5}$ (4) CONFLICTS OF INTEREST. (a) A member of the board shall recuse himself 6 or herself from a decision by the board relating to a prescription drug product if the 7 member or an immediate family member of the member has received or could 8 receive any of the following: 9 1. A direct financial benefit deriving from a determination, or a finding of a 10 study or review, by the board relating to the prescription drug product. 11 2. A financial benefit in excess of \$5,000 in a calendar year from any person 12who owns, manufactures, or provides a prescription drug product to be studied or 13reviewed by the board. 14 (b) A conflict of interest under this subsection shall be disclosed by the board 15when hiring board staff, by the appointing authority when appointing members to 16 the board, and by the board when a member of the board is recused from any 17decision relating to a review of a prescription drug product. 18 (c) A conflict of interest under this subsection shall be disclosed no later than 19 5 days after the conflict is identified, except that, if the conflict is identified within 20 5 days of an open meeting of the board, the conflict shall be disclosed prior to the 21meeting. 22(d) The board shall disclose a conflict of interest under this subsection on the

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23 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.

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

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

601.79 Drug cost affordability review. (1) IDENTIFICATION OF DRUGS.
9 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.

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(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.

9 2. Increased by at least 200 percent during the preceding 12-month period, as
10 determined by the difference between the resulting wholesale acquisition cost and
11 the average of the wholesale acquisition cost reported over the preceding 12
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

1 cycle management, net average price in this state, market competition and context,  $\mathbf{2}$ projected revenue, and the estimated value or cost-effectiveness of the prescription 3 drug product.

4 (c) The failure of a manufacturer to provide the board with information for an  $\mathbf{5}$ affordability review under par. (b) does not affect the authority of the board to 6 conduct the review.

7 (3) AFFORDABILITY CHALLENGE. When conducting an affordability review of a 8 prescription drug product under sub. (2), the board shall determine whether use of 9 the prescription drug product that is fully consistent with the labeling approved by 10 the federal food and drug administration or standard medical practice has led or 11 will lead to an affordability challenge for the health care system in this state, 12including high out-of-pocket costs for patients. To the extent practicable, in 13determining whether a prescription drug product has led or will lead to an 14 affordability challenge, the board shall consider all of the following factors:

15

(a) The wholesale acquisition cost for the prescription drug product sold in 16 this state.

17(b) The average monetary price concession, discount, or rebate the 18 manufacturer provides, or is expected to provide, to health plans in this state as 19 reported by manufacturers and health plans, expressed as a percentage of the 20 wholesale acquisition cost for the prescription drug product under review.

21The total amount of the price concessions, discounts, and rebates the (c) 22manufacturer provides to each pharmacy benefit manager for the prescription drug

1 product under review, as reported by the manufacturer and pharmacy benefit  $\mathbf{2}$ manager and expressed as a percentage of the wholesale acquisition cost. 3 The price at which therapeutic alternatives to the prescription drug (d) 4 product have been sold in this state.  $\mathbf{5}$ (e) The average monetary concession, discount, or rebate the manufacturer 6 provides or is expected to provide to health plan payors and pharmacy benefit 7 managers in this state for therapeutic alternatives to the prescription drug product. 8 (f) The costs to health plans based on patient access consistent with labeled 9 indications by the federal food and drug administration and recognized standard 10 medical practice. 11 (g) The impact on patient access resulting from the cost of the prescription 12drug product relative to insurance benefit design. 13The current or expected dollar value of drug-specific patient access (h) 14 programs that are supported by the manufacturer. 15(i) The relative financial impacts to health, medical, or social services costs 16 that can be quantified and compared to baseline effects of existing therapeutic 17alternatives to the prescription drug product. 18 (j) The average patient copay or other cost sharing for the prescription drug 19 product in this state. 20 (k) Any information a manufacturer chooses to provide. 21(L) Any other factors as determined by the board by rule. 22(4) UPPER PAYMENT LIMIT. (a) If the board determines under sub. (3) that use 23of 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.
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3. Other relevant administrative costs related to the drug.

6 (b) For a prescription drug product identified in sub. (1) (b) or (d) 2., the board 7 shall solicit information from the manufacturer regarding the price increase. To 8 the extent that the price increase is not a result of the need for increased 9 manufacturing capacity or other effort to improve patient access during a public 10 health emergency, the board shall establish an upper payment limit under par. (a) 11 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.

16 Notwithstanding subd. 1., while state-sponsored and state-regulated  $\mathbf{2}$ . 17health plans and health programs shall limit drug reimbursements and drug 18 payment to no more than the upper payment limit established under this 19 subsection, a plan subject to the Employee Retirement Income Security Act of 1974 20 or Part D of Medicare under 42 USC 1395w-101 et seq. may choose to reimburse 21more than the upper payment limit. A provider who dispenses and administers a 22prescription drug product in this state to an individual in this state may not bill a 23payor 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.

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4 (5) PUBLIC INSPECTION. Information submitted to the board under this
5 section shall be open to public inspection only as provided under ss. 19.31 to 19.39.

6 (6) NO PROHIBITION ON MARKETING. Nothing in this section may be construed
7 to prevent a manufacturer from marketing a prescription drug product approved by
8 the federal food and drug administration while the prescription drug product is
9 under review by the board.

10 (7) APPEALS. A person aggrieved by a decision of the board may request an 11 appeal of the decision no later than 30 days after the board makes the 12 determination. The board shall hear the appeal and make a final decision no later 13 than 60 days after the appeal is requested. A person aggrieved by a final decision of 14 the board may petition for judicial review in a court of competent jurisdiction.

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

16 **609.83 Coverage of drugs and devices.** Limited service health 17 organizations, preferred provider plans, and defined network plans are subject to 18 ss. 632.853, 632.861, and 632.895 (6) (b), (16t), and (16v).

19 **SECTION 10.** 632.868 of the statutes is created to read:

20 **632.868 Insulin safety net programs.** (1) DEFINITIONS. In this section:

- (a) "Manufacturer" means a person engaged in the manufacturing of insulinthat is self-administered on an outpatient basis.
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(b) "Navigator" has the meaning given in s. 628.90 (3).

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1	(c) "Patient assistance program" means a program established by a
2	manufacturer under sub. (3) (a).
3	(d) "Pharmacy" means an entity licensed under s. 450.06 or 450.065.
4	(e) "Urgent need of insulin" means having less than a 7-day supply of insulin
5	readily available for use and needing insulin in order to avoid the likelihood of
6	suffering a significant health consequence.
7	(f) "Urgent need safety net program" means a program established by a
8	manufacturer under sub. (2) (a).
9	(2) URGENT NEED SAFETY NET PROGRAM. (a) Establishment of program. No
10	later than July 1, 2026, each manufacturer shall establish an urgent need safety net
11	program to make insulin available in accordance with this subsection to individuals
12	who meet the eligibility requirements under par. (b).
13	(b) <i>Eligible individual</i> . An individual shall be eligible to receive insulin under
14	an urgent need safety net program if all of the following conditions are met:
15	1. The individual is in urgent need of insulin.
16	2. The individual is a resident of this state.
17	3. The individual is not receiving public assistance under ch. 49.
18	4. The individual is not enrolled in prescription drug coverage through an
19	individual or group health plan that limits the total cost sharing amount, including
20	copayments, deductibles, and coinsurance, that an enrollee is required to pay for a
21	30-day supply of insulin to no more than \$75, regardless of the type or amount of
22	insulin prescribed.

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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).

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3 (c) Provision of insulin under an urgent need safety net program. 1. In order
4 to receive insulin under an urgent need safety net program, an individual who
5 meets the eligibility requirements under par. (b) shall provide a pharmacy with all
6 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).

11 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.

152. Upon receipt of the information described in subd. 1. a. to c., the pharmacist 16 shall dispense a 30-day supply of the prescribed insulin to the individual. The 17pharmacy shall also provide the individual with the information sheet described in 18 sub. (8) (b) 2. and the list of navigators described in sub. (8) (c). The pharmacy may 19 collect a copayment, not to exceed \$35, from the individual to cover the pharmacy's 20 costs of processing and dispensing the insulin. The pharmacy shall notify the 21health care practitioner who issued the prescription no later than 72 hours after the 22insulin is dispensed.

23

3. A pharmacy that dispenses insulin under subd. 2. may submit to the

1 manufacturer, or the manufacturer's vendor, a claim for payment that is in 2 accordance with the national council for prescription drug programs' standards for 3 electronic claims processing, except that no claim may be submitted if the 4 manufacturer agrees to send the pharmacy a replacement of the same insulin in 5 the amount dispensed. If the pharmacy submits an electronic claim, the 6 manufacturer or vendor shall reimburse the pharmacy in an amount that covers 7 the pharmacy's acquisition cost.

8 4. A pharmacy that dispenses insulin under subd. 2. shall retain a copy of the9 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:

22

1. Provide the commissioner with information regarding the patient

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1	assistance program, including contact information for individuals to call for
2	assistance in accessing the patient assistance program.
3	2. Provide a hotline for individuals to call or access between 8 a.m. and 10 p.m.
4	on weekdays and between 10 a.m. and 6 p.m. on Saturdays.
5	3. List the eligibility requirements under par. (b) on the manufacturer's
6	website.
7	4. Maintain the privacy of all information received from an individual
8	applying for or participating in the patient assistance program and not sell, share,
9	or disseminate the information unless required under this section or authorized, in
10	writing, by the individual.
11	(b) <i>Eligible individual</i> . An individual shall be eligible to receive insulin under
12	a patient assistance program if all of the following conditions are met:
13	1. The individual is a resident of this state.
14	2. The individual, or the individual's parent or legal guardian if the individual
15	is under the age of 18, has a valid Wisconsin driver's license or state identification
16	card.
17	3. The individual has a valid insulin prescription.
18	4. The family income of the individual does not exceed 400 percent of the
19	poverty line as defined and revised annually under 42 USC 9902 (2) for a family the
20	size of the individual's family.
21	5. The individual is not receiving public assistance under ch. 49.
22	6. The individual is not eligible to receive health care through a federally
23	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.

5 7. The individual is not enrolled in prescription drug coverage through an 6 individual or group health plan that limits the total cost sharing amount, including 7 copayments, deductibles, and coinsurance, that an enrollee is required to pay for a 8 30-day supply of insulin to no more than \$75, regardless of the type or amount of 9 insulin needed.

10 (c) Application for patient assistance program. 1. An individual may apply to 11 participate in a patient assistance program by filing an application with the 12manufacturer that established the patient assistance program, the individual's 13health care practitioner if the practitioner participates in the patient assistance 14 program, or a navigator included on the list under sub. (8) (c). A health care 15practitioner or navigator shall immediately submit the application to the 16 manufacturer. Upon receipt of an application, the manufacturer shall determine 17the individual's eligibility under par. (b) and, except as provided in subd. 2., notify 18 the individual of the determination no later than 10 days after receipt of the 19 application.

20 2. If necessary to determine the individual's eligibility under par. (b), the 21 manufacturer may request additional information from an individual who has filed 22 an application under subd. 1. no later than 5 days after receipt of the application. 23 Upon receipt of the additional information, the manufacturer shall determine the 1

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individual's eligibility under par. (b) and notify the individual of the determination no later than 3 days after receipt of the requested information.

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3 3. Except as provided in subd. 5., if the manufacturer determines under subd. 4 1. or 2. that the individual is eligible for the patient assistance program, the 5 manufacturer shall provide the individual with a statement of eligibility. The 6 statement of eligibility shall be valid for 12 months and may be renewed upon a 7 determination by the manufacturer that the individual continues to meet the 8 eligibility requirements under par. (b).

9 4. If the manufacturer determines under subd. 1. or 2. that the individual is 10 not eligible for the patient assistance program, the manufacturer shall provide the 11 reason for the determination in the notification under subd. 1. or 2. The individual 12may appeal the determination by filing an appeal with the commissioner that shall 13include all of the information provided to the manufacturer under subds. 1. and 2. 14 The commissioner shall establish procedures for deciding appeals under this 15subdivision. The commissioner shall issue a decision no later than 10 days after the 16 appeal is filed, and the commissioner's decision shall be final. If the commissioner 17determines that the individual meets the eligibility requirements under par. (b), the 18 manufacturer shall provide the individual with the statement of eligibility 19 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 1 of the manufacturer's copayment assistance program rather than the patient 2 assistance program, the manufacturer shall inform the individual of the 3 determination and provide the individual with the necessary coupons to submit to 4 a pharmacy. The individual may not be required to pay more than the copayment 5 amount specified in par. (d) 2.

6 (d) Provision of insulin under a patient assistance program. 1. Upon receipt 7 from an individual of the eligibility statement described in par. (c) 3. and a valid 8 insulin prescription, a pharmacy shall submit an order containing the name of the 9 insulin and daily dosage amount to the manufacturer. The pharmacy shall include 10 with the order the pharmacy's name, shipping address, office telephone number, 11 fax number, email address, and contact name, as well as any days or times when 12 deliveries are not accepted by the pharmacy.

132. Upon receipt of an order meeting the requirements under subd. 1., the 14 manufacturer shall send the pharmacy a 90-day supply of insulin, or lesser amount 15if requested in the order, at no charge to the individual or pharmacy. The pharmacy 16 shall dispense the insulin to the individual associated with the order. The insulin 17shall be dispensed at no charge to the individual, except that the pharmacy may 18 collect a copayment from the individual to cover the pharmacy's costs for processing 19 and dispensing in an amount not to exceed \$50 for each 90-day supply of insulin. 20The pharmacy may not seek reimbursement from the manufacturer or a 3rd-party 21payer.

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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.
- 6 (4) EXCEPTIONS. (a) This section does not apply to a manufacturer that shows
  7 to the commissioner's satisfaction that the manufacturer's annual gross revenue
  8 from insulin sales in this state does not exceed \$2,000,000.
- 9 (b) A manufacturer may not be required to make an insulin product available 10 under sub. (2) or (3) if the wholesale acquisition cost of the insulin product does not 11 exceed \$8, as adjusted annually based on the U.S. consumer price index for all 12 urban consumers, U.S. city average, per milliliter or the applicable national council 13 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).

23

(7) REPORTS. (a) Annually, no later than March 1, each manufacturer shall

1	report to the commissioner all of the following information for the previous calendar
2	year:
3	1. The number of individuals who received insulin under the manufacturer's
4	urgent need safety net program.
5	2. The number of individuals who sought assistance under the
6	manufacturer's patient assistance program and the number of individuals who
7	were determined to be ineligible under sub. (3) (c) 4.
8	3. The wholesale acquisition cost of the insulin provided by the manufacturer
9	through the urgent need safety net program and patient assistance program.
10	(b) Annually, no later than April 1, the commissioner shall submit to the
11	governor and the chief clerk of each house of the legislature, for distribution to the
12	legislature under s. 13.172 (2), a report on the urgent need safety net programs and
13	patient assistance programs that includes all of the following:
14	1. The information provided to the commissioner under par. (a).
15	2. The penalties assessed under sub. (9) during the previous calendar year,
16	including the name of the manufacturer and amount of the penalty.
17	(8) ADDITIONAL RESPONSIBILITIES OF COMMISSIONER. (a) Application form.
18	The commissioner shall make the application form described in sub. (2) (c) 1. a.
19	available on the office's website and shall make the form available to pharmacies
20	and health care providers who prescribe or dispense insulin, hospital emergency
21	departments, urgent care clinics, and community health clinics.
22	(b) Public outreach. 1. The commissioner shall conduct public outreach to

create awareness of the urgent need safety net programs and patient assistance
 programs.

3 2. The commissioner shall develop and make available on the office's website
4 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.

7 b. A description of how to access insulin through a patient assistance8 program.

9 c. Information on how to contact a navigator for assistance in accessing 10 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

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1	safety net programs and patient assistance programs. The survey shall ask
2	whether the individual is still in need of a long-term solution for affordable insulin
3	and shall include questions about the individual's satisfaction with all of the
4	following, if applicable:
5	a. Accessibility to urgent-need insulin.
6	b. Adequacy of the information sheet and list of navigators received from the
7	pharmacy.
8	c. Helpfulness of a navigator.
9	d. Ease of access in applying for a patient assistance program and receiving
10	insulin from the pharmacy under the patient assistance program.
11	2. The commissioner shall develop and conduct a satisfaction survey of
12	pharmacies that have dispensed insulin through urgent need safety net programs
13	and patient assistance programs. The survey shall include questions about the
14	pharmacy's satisfaction with all of the following, if applicable:
15	a. Timeliness of reimbursement from manufacturers for insulin dispensed by
16	the pharmacy under urgent need safety net programs.
17	b. Ease in submitting insulin orders to manufacturers.
18	c. Timeliness of receiving insulin orders from manufacturers.
19	3. The commissioner may contract with a nonprofit entity to develop and
20	conduct the surveys under subds. 1. and 2. and to evaluate the survey results.
21	4. No later than July 1, 2028, the commissioner shall submit to the governor
22	and the chief clerk of each house of the legislature, for distribution to the legislature
23	under s. 13.172 (2), a report on the results of the surveys under subds. 1. and 2.

1	(9) PENALTY. A manufacturer that violates this section may be required to
2	forfeit not more than \$200,000 per month of violation, with the maximum forfeiture
3	increasing to \$400,000 per month if the manufacturer continues to be in violation
4	after 6 months and increasing to \$600,000 per month if the manufacturer continues
5	to be in violation after one year.
6	SECTION 11. 632.895 (6) (title) of the statutes is amended to read:
7	632.895 (6) (title) Equipment and supplies for treatment of diabetes;
8	INSULIN.
9	<b>SECTION 12.</b> 632.895 (6) of the statutes is renumbered 632.895 (6) (a) and
10	amended to read:
11	632.895 (6) (a) Every disability insurance policy which that provides coverage
12	of expenses incurred for treatment of diabetes shall provide coverage for expenses
13	incurred by the installation and use of an insulin infusion pump, coverage for all
14	other equipment and supplies, including insulin or any other prescription
15	medication, used in the treatment of diabetes, and coverage of diabetic self-
16	management education programs. Coverage Except as provided in par. (b),
17	coverage required under this subsection shall be subject to the same exclusions,
18	limitations, deductibles, and coinsurance provisions of the policy as other covered
19	expenses, except that insulin infusion pump coverage may be limited to the
20	purchase of one pump per year and the insurer may require the insured to use a
21	pump for 30 days before purchase.
22	<b>SECTION 13</b> , 632 895 (6) (b) of the statutes is created to read:

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

23 632.895 (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.

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b. "Self-insured health plan" has the meaning given in s. 632.85 (1) (c).

5 2. Every disability insurance policy and self-insured health plan that covers 6 insulin and imposes cost sharing on prescription drugs may not impose cost sharing 7 on insulin in an amount that exceeds \$35 for a one-month supply of insulin.

8 3. Nothing in this paragraph prohibits a disability insurance policy or self-9 insured health plan from imposing cost sharing on insulin in an amount less than 10 the amount specified under subd. 2. Nothing in this paragraph requires a disability 11 insurance policy or self-insured health plan to impose any cost sharing on insulin.

12

## 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).

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

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### SECTION 9223. Fiscal changes; Insurance.

8 (1) OFFICE OF PRESCRIPTION DRUG AFFORDABILITY. In the schedule under s. 9 20.005 (3) for the appropriation to the office of the commissioner of insurance under 10 s. 20.145(1)(g), the dollar amount for fiscal year 2025-26 is increased by \$1.957,30011 to provide \$500,000 in onetime implementation costs for establishing an office of 12prescription drug affordability in the office of the commissioner of insurance and 13 \$1,457,300 to authorize 16.0 PR positions within the office of prescription drug 14 affordability, including 5.0 insurance examiners, 4.0 policy initiatives advisors, 2.0 15attorneys, 1.0 insurance program manager, 2.0 insurance administrators, and 2.0 16 operations program associates. In the schedule under s. 20.005 (3) for the 17appropriation to the office of the commissioner of insurance under s. 20.145 (1) (g), 18 the dollar amount for fiscal year 2026-27 is increased by \$1,871,100 to fund the 19 positions authorized under this subsection.

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#### **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.".

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(END)