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LRB-1302/1 JPC:all

# 2025 ASSEMBLY BILL 62

February 24, 2025 - Introduced by Representatives Subeck, Spaude, Johnson, Anderson, Andraca, Arney, Bare, Billings, Brown, Cruz, DeSanto, DeSmidt, Doyle, Emerson, Fitzgerald, Goodwin, Haywood, Hong, Hysell, J. Jacobson, Joers, Kirsch, Madison, Mayadev, McCarville, McGuire, Miresse, Moore Omokunde, Neubauer, Ortiz-Velez, Palmeri, Phelps, Prado, Rivera-Wagner, Roe, Sheehan, Sinicki, Snodgrass, Stroud, Stubbs, Taylor, Tenorio, Udell and Vining, cosponsored by Senators Pfaff, Hesselbein, Drake, Carpenter, Dassler-Alfheim, Habush Sinykin, L. Johnson, Keyeski, Ratcliff, Roys, Smith, Spreitzer, Wall and Wirch. Referred to Committee on Health, Aging and Long-Term Care.

# AN ACT to repeal 49.45 (18) (ag); to renumber and amend 632.895 (6); to

amend 49.45 (18) (ac), 609.83 and 632.895 (6) (title); to create 15.07 (3) (bm) 7., 15.735, 20.145 (1) (a), 20.145 (1) (g) 4., 49.45 (18) (b) 8., 255.056 (2g), 450.085 (3), 601.31 (1) (nv), 601.31 (1) (nw), 601.41 (14), 601.415 (14), 601.56, 601.57, 601.575, subchapter VI of chapter 601 [precedes 601.78], 632.865 (2m), 632.868, 632.869 and 632.895 (6) (b) of the statutes; relating to: health care costs omnibus, granting rule-making authority, making an appropriation, and providing a penalty.

# Analysis by the Legislative Reference Bureau

# Elimination of cost sharing for prescription drugs under the Medical Assistance program

Under current law, certain persons who receive health services under the Medical Assistance program, also known in this state as BadgerCare, are required to contribute a cost-sharing payment to the cost of certain health services. This bill eliminates all cost-sharing payments for prescription drugs under the Medical

Assistance program. The Medical Assistance program is a joint state and federal program that provides health services to individuals who have limited financial resources.

## Cost-sharing cap on insulin

The bill prohibits every health insurance policy and governmental self-insured health plan that covers insulin and imposes cost sharing on prescription drugs from imposing cost sharing on insulin in an amount that exceeds \$35 for a one-month supply. Current law requires every health insurance policy that provides coverage of expenses incurred for treatment of diabetes to provide coverage for specified expenses and items, including insulin. The required coverage under current law for certain diabetes treatments other than insulin infusion pumps is subject to the same exclusions, limitations, deductibles, and coinsurance provisions of the policy as other covered expenses. The bill's cost-sharing limitation on insulin supersedes the specification that the exclusions, limitations, deductibles, and coinsurance are the same as for other coverage.

## Fiduciary and disclosure requirements for pharmacy benefit managers

The bill imposes fiduciary and disclosure requirements on pharmacy benefit managers. Pharmacy benefit managers contract with health plans that provide prescription drug benefits to administer those benefits for the plans. They also have contracts with pharmacies and pay the pharmacies for providing drugs to the plan beneficiaries.

The bill provides that a pharmacy benefit manager owes a fiduciary duty to a health plan sponsor. The bill also requires that a pharmacy benefit manager annually disclose all of the following information to the plan sponsor:

- 1. The indirect profit received by the pharmacy benefit manager from owning a pharmacy or service provider.
- 2. Any payments made to a consultant or broker who works on behalf of the plan sponsor.
- 3. From the amounts received from drug manufacturers, the amounts retained by the pharmacy benefit manager that are related to the plan sponsor's claims or bona fide service fees.
- 4. The amounts received from network pharmacies and the amount retained by the pharmacy benefit manager.

# Reimbursements for certain 340B program entities

The bill prohibits any person from reimbursing certain entities that participate in the federal drug pricing program, known as the 340B program, for a drug subject to an agreement under the program at a rate lower than that paid for the same drug to pharmacies that have a similar prescription volume. The bill also prohibits a person from imposing any fee, charge back, or other adjustment on the basis of the entity's participation in the 340B program. The entities covered by the prohibitions under the bill are federally qualified health centers, critical access hospitals, and grantees under the federal Ryan White HIV/AIDS program, as well

as these entities' pharmacies and any pharmacy with which any of the entities have contracted to dispense drugs through the 340B program.

## Drug repository program

Under current law, the Department of Health Services must maintain a drug repository program under which any person may donate certain drugs or supplies to be dispensed to and used by eligible individuals, prioritizing uninsured and indigent individuals. The bill allows DHS to partner with out-of-state drug repository programs. The bill also allows out-of-state persons to donate to the drug repository program in Wisconsin and persons in Wisconsin to donate to participating drug repository programs in other states. Further, the bill directs DHS to study and implement a centralized, physical drug repository program.

## Value-based diabetes medication pilot project

The bill directs the Office of the Commissioner of Insurance to develop a pilot project under which a pharmacy benefit manager and pharmaceutical manufacturer are directed to create a value-based, sole-source arrangement to reduce the costs of prescription diabetes medication. The bill allows OCI to promulgate rules to implement the pilot project.

# Pharmacist continuing education credits for volunteering at free and charitable clinics

Under current law, a licensed pharmacist must renew his or her license every two years. An applicant for renewal of a pharmacist license must submit proof that he or she has completed 30 hours of continuing education within the two-year period immediately preceding the date of his or her application. The bill allows pharmacists to meet up to 10 hours of the continuing education requirement for each two-year period by volunteering at a free and charitable clinic approved by the Pharmacy Examining Board.

## Prescription drug importation program

The bill requires the commissioner of insurance, in consultation with persons interested in the sale and pricing of prescription drugs and federal officials and agencies, to design and implement a prescription drug importation program for the benefit of and that generates savings for Wisconsin residents. The bill establishes requirements for the program, including all of the following:

- 1. The commissioner must designate a state agency to become a licensed wholesale distributor or contract with a licensed wholesale distributor and to seek federal certification and approval to import prescription drugs.
- 2. The program must comply with certain federal regulations and import from Canadian suppliers only prescription drugs that are not brand-name drugs, have fewer than four competitor drugs in this country, and for which importation creates substantial savings.
- 3. The commissioner must ensure that prescription drugs imported under the program are not distributed, dispensed, or sold outside of Wisconsin.

4. The program must have an audit procedure to ensure the program complies with certain requirements specified in the bill.

Before submitting the proposed program to the federal government for certification, the commissioner must submit the proposed program to the Joint Committee on Finance for its approval.

## Pharmacy benefits tool grants

The bill directs OCI to award grants in an amount of up to \$500,000 in each fiscal year to health care providers to develop and implement a patient pharmacy benefits tool that would allow prescribers to disclose the cost of prescription drugs for patients. The tool must be usable by physicians and other prescribers to determine the cost of prescription drugs for their patients. Any health care provider that receives a grant to develop and implement a patient pharmacy benefits tool is required to contribute matching funds equal to at least 50 percent of the total grant awarded.

## Prescription drug purchasing entity study

The bill requires OCI to conduct a study on the viability of creating or implementing a state prescription drug purchasing entity.

### Licensure of pharmacy services administrative organizations

The bill requires that a pharmacy services administrative organization (PSAO) be licensed by OCI. Under the bill, a PSAO is an entity operating in Wisconsin that does all of the following:

- 1. Contracts with an independent pharmacy to conduct business on the pharmacy's behalf with a third-party payer.
- 2. Provides at least one administrative service to an independent pharmacy and negotiates and enters into a contract with a third-party payer or pharmacy benefit manager on the pharmacy's behalf.

The bill defines "independent pharmacy" to mean a licensed pharmacy operating in Wisconsin that is under common ownership with no more than two other pharmacies. "Administrative service" is defined to mean assisting with claims or audits, providing centralized payment, performing certification in a specialized care program, providing compliance support, setting flat fees for generic drugs, assisting with store layout, managing inventory, providing marketing support, providing management and analysis of payment and drug dispensing data, or providing resources for retail cash cards. The bill defines "third-party payer" to mean an entity operating in Wisconsin that pays or insures health, medical, or prescription drug expenses on behalf of beneficiaries. The bill uses the current law definition of "pharmacy benefit manager," which is an entity doing business in Wisconsin that contracts to administer or manage prescription drug benefits on behalf of an insurer or other entity that provides prescription drug benefits to Wisconsin residents.

To obtain the license required by the bill, a person must apply to OCI and provide the contact information for the applicant and a contact person, evidence of

financial responsibility of at least \$1,000,000, and any other information required by the commissioner by rule. Under the bill, the license fee is set by the commissioner, and the term of a license is two years.

The bill also requires that a PSAO disclose to OCI the extent of any ownership or control by an entity that provides pharmacy services; provides prescription drug or device services; or manufactures, sells, or distributes prescription drugs, biologicals, or medical devices. The PSAO must notify OCI within five days of any material change in its ownership or control related to such an entity.

# $Licensure\ of\ pharmaceutical\ representatives$

The bill requires a pharmaceutical representative to be licensed by OCI and to display the pharmaceutical representative's license during each visit with a health care professional. The bill defines "pharmaceutical representative" to mean an individual who markets or promotes pharmaceuticals to health care professionals on behalf of a pharmaceutical manufacturer for compensation.

The term of a license issued under the bill is one year, and the license is renewable. The application to obtain or renew a license must include the applicant's contact information, a description of the type of work in which the applicant will engage, the license fee, an attestation that professional education requirements are met, proof that any penalties and other fees are paid, and any other information required by OCI by rule. Under the bill, the license fee is set by the commissioner. The bill requires the pharmaceutical representative to report, within four business days, any change to the information provided on the application or any material change to the pharmaceutical representative's business operations or other information required to be reported under the bill.

The bill requires that a pharmaceutical representative complete a professional education course prior to becoming licensed and to annually complete at least five hours of continuing professional education courses. The coursework must include, at a minimum, training in ethical standards, whistleblower protections, and the laws and rules applicable to pharmaceutical marketing. The bill directs the commissioner to regularly publish a list of courses that fulfill the education requirements. Under the bill, a course provider must disclose any conflict of interest to the commissioner, and the courses may not be provided by the employer of a pharmaceutical representative or be funded by the pharmaceutical industry or a third party funded by the industry.

The bill requires that, no later than June 1 of each year, a pharmaceutical representative report to OCI the pharmaceutical representative's total number of contacts with health care professionals in Wisconsin, the specialties of those health care professionals, the location and duration of each contact, the pharmaceuticals discussed, and the value of any item provided to a health care professional. The bill directs the commissioner to publish the information on OCI's website without identifying individual health care professionals.

The bill requires that a pharmaceutical representative, during each contact with a health care professional, disclose the wholesale acquisition cost of any

pharmaceuticals discussed and the names of at least three generic prescription drugs from the same therapeutic class.

The bill directs the commissioner to promulgate ethical standards for pharmaceutical representatives. Additionally, the bill prohibits a pharmaceutical representative from engaging in deceptive or misleading marketing of a pharmaceutical product; using a title or designation that could reasonably lead a licensed health care professional, or an employee or representative of such a professional, to believe that the pharmaceutical representative is licensed to practice in a health occupation unless the pharmaceutical representative holds a license to practice in that health occupation; or attending a patient examination without the patient's consent.

An individual who violates any of the requirements under the bill is subject to a forfeiture, and the individual's license may be suspended or revoked. An individual whose license is revoked must wait at least two years before applying for a new license.

## Insulin safety net programs

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

The bill also requires that each insulin manufacturer establish a patient assistance program to make insulin available to any qualifying Wisconsin resident who, among other requirements, is uninsured or has limited insurance coverage and whose family income does not exceed 400 percent of the federal poverty line. Under the bill, an individual must apply to participate in a manufacturer's program. If the manufacturer determines that the individual meets the program's eligibility requirements, the manufacturer must issue the individual a statement of eligibility, which is valid for 12 months and may be renewed. Under the bill, if an individual with a statement of eligibility and valid insulin prescription requests insulin from a pharmacy, the pharmacy must submit an order to the manufacturer, who must then provide a 90-day supply of insulin at no charge to the individual or pharmacy. The pharmacy may charge the individual a copayment of no more than \$50. Under the bill, a manufacturer is not required to issue a statement of eligibility if the individual has prescription drug coverage through an individual or

group health plan and the manufacturer determines that the individual's insulin needs are better addressed through the manufacturer's copayment assistance program. In such case, the manufacturer must provide the individual with necessary drug coupons to submit to a pharmacy, and the individual may not be required to pay more than a \$50 copayment for a 90-day supply of insulin.

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

The bill requires that insulin manufacturers annually report to OCI certain information, including the number of individuals served and the cost of insulin dispensed under the programs and that OCI annually report to the governor and the legislature on the programs. The bill also directs OCI to conduct public outreach and develop an information sheet about the programs, conduct satisfaction surveys of individuals and pharmacies that participate in the programs, and report to the governor and the legislature on the surveys by July 1, 2028. Additionally, the bill requires that OCI develop a training program for health care navigators to assist individuals in accessing appropriate long-term insulin options and maintain a list of trained navigators.

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

## Prescription Drug Affordability Review Board

The bill creates a Prescription Drug Affordability Review Board, whose purpose is to protect Wisconsin residents and other stakeholders from the high costs of prescription drugs. The board consists of the commissioner of insurance and the following members, all of whom are appointed by the governor for four-year terms:

- 1. Two members who represent the pharmaceutical drug industry, at least one of whom is a licensed pharmacist.
  - 2. Two members who represent the health insurance industry.
- 3. Two members who represent the health care industry, at least one of whom is a licensed practitioner.
  - 4. Two members who represent the interests of the public.

The bill requires the board to meet in open session at least four times per year to review prescription drug pricing information. The board must provide at least two weeks' public notice of each meeting, make the meeting's materials publicly available at least one week prior to the meeting, and provide the opportunity for

public comment. The bill imposes conflict of interest requirements for the board relating to recusal and public disclosure of certain conflicts. The bill directs the board to access and assess drug pricing information, to the extent practicable, by accessing and assessing information from other states, by assessing spending for the drug in Wisconsin, and by accessing other available pricing information.

Under the bill, the board must conduct drug cost affordability reviews. The board must identify prescription drugs whose launch wholesale acquisition cost exceeds specified thresholds, prescription drugs whose increase in wholesale acquisition cost exceeds specified thresholds, and other prescription drugs that may create affordability challenges for the health care system in Wisconsin. For each identified prescription drug, the board must determine whether to conduct an affordability review by seeking stakeholder input and considering the average patient cost share for the drug. During an affordability review, the board must determine whether use of the prescription drug 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 Wisconsin. In making this determination, the bill requires the board to consider a variety of factors, which include the following:

- 1. The drug's wholesale acquisition cost.
- 2. The average monetary price concession, discount, or rebate the manufacturer provides, or is expected to provide, for the drug to health plans.
- 3. The total amount of price concessions, discounts, and rebates the manufacturer provides to each pharmacy benefit manager for the drug.
- 4. The price at which therapeutic alternatives have been sold and the average monetary concession, discount, or rebate the manufacturer provides, or is expected to provide, to health plan payors and pharmacy benefit managers for therapeutic alternatives.
- 5. The costs to health plans based on patient access consistent with federal labeled indications and recognized standard medical practice.
- 6. The impact on patient access resulting from the drug's cost relative to insurance benefit design.
- 7. The current or expected dollar value of drug-specific patient access programs that are supported by the manufacturer.
- 8. The relative financial impacts to health, medical, or social services costs that can be quantified and compared to baseline effects of existing therapeutic alternatives.
  - 9. The average patient copay or other cost sharing for the drug.

If the board determines that a prescription drug will lead to an affordability challenge, the bill directs the board to establish an upper payment limit for that drug that applies to all purchases and payor reimbursements of the drug dispensed or administered to individuals in Wisconsin. In establishing the upper payment limit, the board must consider the cost of administering the drug, the cost of delivering it to consumers, and other relevant administrative costs. For certain

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drugs, the board must solicit information from the manufacturer regarding the price increase and, if the board determines 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 must establish an upper payment limit equal to the drug's cost prior to the price increase.

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Further, this bill provides \$500,000 in program revenue in fiscal year 2026–27 for onetime implementation costs associated with establishing an Office of Prescription Drug Affordability in OCI. The bill provides that the Office of Prescription Drug Affordability is responsible for prescription drug affordability programming within OCI and for overseeing the operations of the Prescription Drug Affordability Review Board. Additionally, the bill authorizes and funds for fiscal year 2026–27 16.0 positions for the Office of Prescription Drug Affordability.

Finally, the bill credits to the appropriation account for OCI's general program operations all moneys received from the regulation of pharmacy benefit managers, pharmacy benefit management brokers, pharmacy benefit management consultants, pharmacy services administrative organizations, and pharmaceutical sales representatives.

This proposal may contain a health insurance mandate requiring a social and financial impact report under s. 601.423, stats.

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

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

- **SECTION 1.** 15.07 (3) (bm) 7. of the statutes is created to read:
- 2 15.07 (3) (bm) 7. The prescription drug affordability review board shall meet 3 at least 4 times each year.
- **SECTION 2.** 15.735 of the statutes is created to read:

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- 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

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- pharmaceutical drug industry, including pharmaceutical drug manufacturers and wholesalers. At least one of the members appointed under this paragraph shall be a pharmacist licensed in this state.
  - (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 health care 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.** 20.005 (3) (schedule) of the statutes: at the appropriate place, insert the following amounts for the purposes indicated:

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1			2025-26	2026-27
2	20.145	Insurance, office of the commissioner of		

- 20.145 Insurance, office of the commissioner of
- 3 **(1)** SUPERVISION OF THE INSURANCE INDUSTRY
- 4 (a) State operations **GPR** A 500,000 -0-
- 5 **SECTION 4.** 20.145 (1) (a) of the statutes is created to read:
- 6 20.145 (1) (a) State operations. The amounts in the schedule for general 7 program operations.
- 8 **SECTION 5.** 20.145 (1) (g) 4. of the statutes is created to read:
  - 20.145 (1) (g) 4. All moneys received from the regulation of pharmacy benefit managers, pharmacy benefit management brokers, pharmacy benefit management consultants, pharmacy services administrative organizations, and pharmaceutical sales representatives.
  - **SECTION 6.** 49.45 (18) (ac) of the statutes is amended to read:
  - 49.45 (18) (ac) Except as provided in pars. (am) to (d), and subject to par. (ag), any person eligible for medical assistance under s. 49.46, 49.468, or 49.47, or for the benefits under s. 49.46 (2) (a) and (b) under s. 49.471, shall pay up to the maximum amounts allowable under 42 CFR 447.53 to 447.58 for purchases of services provided under s. 49.46 (2). The service provider shall collect the specified or allowable copayment, coinsurance, or deductible, unless the service provider determines that the cost of collecting the copayment, coinsurance, or deductible exceeds the amount to be collected. The department shall reduce payments to each provider by the amount of the specified or allowable copayment, coinsurance, or deductible. No provider may deny care or services because the recipient is unable to

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commissioner by rule.

1	share costs, but an inability to share costs specified in this subsection does not
2	relieve the recipient of liability for these costs.
3	SECTION 7. 49.45 (18) (ag) of the statutes is repealed.
4	<b>SECTION 8.</b> 49.45 (18) (b) 8. of the statutes is created to read:
5	49.45 (18) (b) 8. Prescription drugs.
6	<b>SECTION 9.</b> 255.056 (2g) of the statutes is created to read:
7	255.056 (2g) The department may partner with out-of-state drug repository
8	programs. The department may authorize a medical facility or pharmacy that
9	elects to participate in the drug repository program to receive drugs or supplies
10	from out of state, and the department may authorize an out-of-state entity that
11	participates in a partner out-of-state drug repository program to receive drugs or
12	supplies from Wisconsin.
13	<b>SECTION 10.</b> 450.085 (3) of the statutes is created to read:
14	450.085 (3) An applicant for renewal of a license under s. 450.08 (2) (a) may
15	count, for purposes of the continuing education requirement under sub. (1), up to $10$
16	hours spent as a volunteer at a free and charitable clinic approved by the board.
17	<b>SECTION 11.</b> 601.31 (1) (nv) of the statutes is created to read:
18	601.31 (1) (nv) For issuing or renewing a license as a pharmaceutical
19	representative under s. 601.56, an amount to be set by the commissioner by rule.
20	<b>SECTION 12.</b> 601.31 (1) (nw) of the statutes is created to read:
21	601.31 (1) (nw) For issuing or renewing a license as a pharmacy services
22	administrative organization under s. 601.57, an amount to be set by the

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1	SECTION 13.	601.41	(14) of the sta	atutes is	created to	read:

- 601.41 (14) VALUE-BASED DIABETES MEDICATION PILOT PROJECT. The commissioner shall develop a pilot project to direct a pharmacy benefit manager, as defined in s. 632.865 (1) (c), and a pharmaceutical manufacturer to create a value-based, sole-source arrangement to reduce the costs of prescription medication used to treat diabetes. The commissioner may promulgate rules to implement this subsection.
  - **SECTION 14.** 601.415 (14) of the statutes is created to read:
- 601.415 (14) PATIENT PHARMACY BENEFITS TOOL. (a) From the appropriation under s. 20.145 (1) (a), beginning in the 2026-27 fiscal year, the office shall award grants in a total amount of up to \$500,000 each fiscal year to health care providers to develop and implement a tool for prescribers to disclose the cost of prescription drugs for patients. The tool must be usable by physicians and other prescribers to determine the cost of prescription drugs for their patients.
- (b) Any health care provider that receives a grant under par. (a) shall contribute matching funds equal to at least 50 percent of the grant amount awarded.
- **SECTION 15.** 601.56 of the statutes is created to read:
- **601.56 Pharmaceutical representatives.** (1) DEFINITIONS. In this 20 section:
  - (a) "Health care professional" means a physician or other health care practitioner who is licensed to provide health care services or to prescribe pharmaceutical or biologic products.

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- (b) "Pharmaceutical" means a medication that may legally be dispensed only with a valid prescription from a health care professional.
  - (c) "Pharmaceutical representative" means an individual who markets or promotes pharmaceuticals to health care professionals on behalf of a pharmaceutical manufacturer for compensation.
  - (d) "Wholesale acquisition cost" means the most recently reported manufacturer list or catalog price for a brand-name or generic drug available to wholesalers or direct purchasers in the United States, before application of discounts, rebates, or reductions in price.
  - (2) LICENSURE. (a) No individual may act as a pharmaceutical representative in this state without being licensed by the commissioner as a pharmaceutical representative under this section. In order to obtain or renew a license, the individual shall apply to the commissioner in the form and manner prescribed by the commissioner. The term of a license issued under this paragraph is one year and is renewable. The application to obtain or renew a license shall include all of the following information:
  - 1. The applicant's full name, residence address and telephone number, and business address and telephone number.
    - 2. A description of the type of work in which the applicant will engage.
    - 3. The fee under s. 601.31 (1) (nv).
- 4. An attestation that the applicant meets the professional education requirements under sub. (3).
  - 5. Proof that the applicant has paid any assessed penalties and fees.

- 6. Any other information required by the commissioner by rule.
- 2 (b) The pharmaceutical representative licensed under par. (a) shall notify the commissioner in writing of any change to the information submitted on an application under par. (a) or any material change to the pharmaceutical representative's business operations or to any other information provided under this section. The pharmaceutical representative shall provide the notification no later than 4 business days after the change or material change occurs.
  - (c) A pharmaceutical representative licensed under par. (a) shall display the pharmaceutical representative's license during each visit with a health care professional.
  - (3) PROFESSIONAL EDUCATION REQUIREMENTS. (a) In order to become initially licensed under sub. (2) (a), a pharmaceutical representative shall complete a professional education course approved by the commissioner. A pharmaceutical representative shall, upon request, provide the commissioner with proof that he or she has completed an approved professional education course.
  - (b) In order to renew a license under sub. (2) (a), a pharmaceutical representative shall complete a minimum of 5 hours of continuing professional education courses. A pharmaceutical representative who has renewed a license under sub. (2) (a) shall, upon request, provide the commissioner with proof that he or she has completed a minimum of 5 hours of continuing professional education courses.
  - (c) The professional education coursework required under pars. (a) and (b) shall include training in ethical standards, whistleblower protections, laws and

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rules applicable to pharmaceutical marketing, and other subjects that the commissioner identifies by rule.

- (d) The commissioner shall regularly designate courses that fulfill the requirements under this subsection and publish a list of the designated courses.
- (e) The professional education coursework required under this subsection may not be provided by the employer of a pharmaceutical representative or be funded, in any way, by the pharmaceutical industry or a 3rd party funded by the pharmaceutical industry. A provider of a course designated under par. (d) shall disclose any conflict of interest to the commissioner.
- (4) DISCLOSURE TO COMMISSIONER. (a) No later than June 1 of each year, a pharmaceutical representative licensed under sub. (2) (a) shall provide to the commissioner, in the manner prescribed by the commissioner, all of the following information from the previous calendar year:
- 1. The total number of times the pharmaceutical representative contacted health care professionals in this state and the specialties of the health care professionals contacted.
- 2. For each contact with a health care professional in this state, the location and duration of the contact, the pharmaceuticals for which the pharmaceutical representative provided information, and the value of any item, including a product sample, compensation, material, or gift, provided to the health care professional.
- (b) The commissioner shall publish the information received under par. (a) on the commissioner's website in a manner in which individual health care professionals are not identifiable by name or other identifiers.

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- (5) DISCLOSURE TO HEALTH CARE PROFESSIONALS. During each contact with a health care professional, a pharmaceutical representative licensed under sub. (2) (a) shall disclose the wholesale acquisition cost of any pharmaceutical for which the pharmaceutical representative provides information and the names of at least 3 generic prescription drugs from the same therapeutic class or, if 3 are not available, as many as are available for prescriptive use.
- (6) ETHICAL STANDARDS. The commissioner shall promulgate rules that contain ethical standards for pharmaceutical representatives and shall publish the ethical standards on the commissioner's website. A pharmaceutical representative licensed under sub. (2) (a) shall comply with the ethical standards contained in the rules and may not do any of the following:
- (a) Engage in deceptive or misleading marketing of a pharmaceutical, including the knowing concealment, suppression, omission, misleading representation, or misstatement of a material fact.
- (b) Use a title or designation that could reasonably lead a licensed health care professional, or an employee or representative of a licensed health care professional, to believe that the pharmaceutical representative is licensed to practice medicine, nursing, dentistry, optometry, pharmacy, or other similar health occupation in this state unless the pharmaceutical representative holds that license to practice.
  - (c) Attend a patient examination without the patient's consent.
- (7) ENFORCEMENT. (a) Any individual who violates this section shall be required to forfeit not less than \$1,000 nor more than \$3,000 for each offense. Each day of continued violation constitutes a separate offense.

7. Assisting with store layout.

(b) The commissioner may suspend or revoke the license of a pharmaceutical
representative who violates this section. A suspended or revoked license may not be
reinstated until the pharmaceutical representative remedies all violations related
to the suspension or revocation and pays all assessed penalties and fees. A
pharmaceutical representative whose license is revoked for any cause may not be
issued a license under sub. (2) (a) until at least 2 years after the date of revocation.
(c) A health care professional who meets with a pharmaceutical
representative who does not display the pharmaceutical representative's license or
share the information required under sub. (5) may report the pharmaceutical
representative to the commissioner.
(8) RULES. The commissioner may promulgate rules to implement this
section.
<b>SECTION 16.</b> 601.57 of the statutes is created to read:
601.57 Pharmacy services administrative organizations. (1)
DEFINITIONS. In this section:
(a) "Administrative service" means any of the following:
1. Assisting with claims.
2. Assisting with audits.
3. Providing centralized payment.
4. Performing certification in a specialized care program.
5. Providing compliance support.
6. Setting flat fees for generic drugs.

**SECTION 16** 

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- 2 9. Providing marketing support.
- 3 10. Providing management and analysis of payment and drug dispensing data.
  - 11. Providing resources for retail cash cards.
- 6 (b) "Independent pharmacy" means a pharmacy operating in this state that is
  7 licensed under s. 450.06 or 450.065 and is under common ownership with no more
  8 than 2 other pharmacies.
  - (c) "Pharmacy benefit manager" has the meaning given in s. 632.865 (1) (c).
- 10 (d) "Pharmacy services administrative organization" means an entity
  11 operating in this state that does all of the following:
- 1. Contracts with an independent pharmacy to conduct business on the independent pharmacy's behalf with a 3rd-party payer.
  - 2. Provides at least one administrative service to an independent pharmacy and negotiates and enters into a contract with a 3rd-party payer or pharmacy benefit manager on behalf of the independent pharmacy.
  - (e) "Third-party payer" means an entity, including a plan sponsor, health maintenance organization, or insurer, operating in this state that pays or insures health, medical, or prescription drug expenses on behalf of beneficiaries.
  - (2) LICENSURE. (a) No person may operate as a pharmacy services administrative organization in this state without being licensed by the commissioner as a pharmacy services administrative organization under this section. In order to obtain or renew a license, the person shall apply to the

SECTION 16

- 1 commissioner in the form and manner prescribed by the commissioner. The application shall include all of the following:
- The name, address, telephone number, and federal employer identification
   number of the applicant.
- 52. The name, business address, and telephone number of a contact person for6the applicant.
- 7 3. The fee under s. 601.31 (1) (nw).

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- 4. Evidence of financial responsibility of at least \$1,000,000.
- 5. Any other information required by the commissioner by rule.
- 10 (b) The term of a license issued under par. (a) shall be 2 years from the date of issuance.
  - (3) DISCLOSURE TO THE COMMISSIONER. (a) A pharmacy services administrative organization licensed under sub. (2) shall disclose to the commissioner the extent of any ownership or control of the pharmacy services administrative organization by an entity that does any of the following:
    - 1. Provides pharmacy services.
    - 2. Provides prescription drug or device services.
- 3. Manufactures, sells, or distributes prescription drugs, biologicals, or
   medical devices.
  - (b) A pharmacy services administrative organization licensed under sub. (2) shall notify the commissioner in writing within 5 days of any material change in its ownership or control relating to an entity described in par. (a).

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(4)	RULES.	The commissioner	may	promulgate	rules	to	implement	this
section.								

- **SECTION 17.** 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.

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- (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

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- 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.

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- 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 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

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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 exten
the action is in accordance with other state laws and the certification by the federa
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.

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**SECTION 17** 

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) RULE MAKING. The commissioner may promulgate any rules necessary to
18	implement this section.
19	SECTION 18. Subchapter VI of chapter 601 [precedes 601.78] of the statutes is
20	created to read:

CHAPTER 601

SUBCHAPTER VI

1	PRESCRIPTION DRUG
2	AFFORDABILITY REVIEW BOARD
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) "Drug product" means a brand name drug, a generic drug, a biologic, a
14	biosimilar, or an over-the-counter drug.
15	(6) "Financial benefit" includes an honorarium, a fee, a stock, the value of the
16	stock holdings of a member of the board or any immediate family member, and any
17	direct financial benefit deriving from the finding of a review conducted under s.
18	601.79.
19	(7) "Generic drug" means any of the following:
20	(a) A retail drug that is marketed or distributed in accordance with an
21	abbreviated new drug application approved under 21 USC 355 (j).
22	(b) An authorized generic drug, as defined in 42 CFR 447.502.

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prescription drug products.

**SECTION 18** 

1	(c) A drug that entered the market prior to 1962 and was not originally
2	marketed under a new drug application.
3	(8) "Immediate family member" means a spouse, grandparent, parent,
4	sibling, child, stepchild, or grandchild or the spouse of a grandparent, parent,
5	sibling, child, stepchild, or grandchild.
6	(9) "Manufacturer" means an entity that does all of the following:
7	(a) Engages in the manufacture of a drug product or enters into a lease with
8	another manufacturer to market and distribute a prescription drug product under
9	the entity's own name.
10	(b) Sets or changes the wholesale acquisition cost of the drug product or
11	prescription drug product described in par. (a).
12	(10) "Over-the-counter drug" means a drug intended for human use that does
13	not require a prescription and meets the requirements of 21 CFR parts 328 to 369.
14	(11) "Pharmacy benefit manager" has the meaning given in s. 632.865 (1) (c).
15	(12) "Prescription drug product" means a brand name drug, a generic drug, a
16	biologic, or a biosimilar.
17	601.785 Prescription drug affordability review board. (1) MISSION.
18	The purpose of the board is to protect state residents, the state, local governments,
19	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

1. Meet in open session at least 4 times per year to review prescription drug

(2) POWERS AND DUTIES. (a) The board shall do all of the following:

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- product pricing information, except that the chair may cancel or postpone a meeting if there is no business to transact.
- 3 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 as described in this subsection. Unless written permission is granted by the board, a 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.

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- (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 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

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- 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 chair 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.
- 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 at least \$3,000 during a 12-month period.
- (c) A biosimilar that has a launch wholesale acquisition cost that is not 15 percent or more 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

**SECTION 18** 

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

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- 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

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- 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.
- 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 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. An upper payment limit established under par. (a) 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 par. (a), 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

1	42 USC	1395w-101	et seq	. chooses	to	reimburse	the	provider	above	the	upper
2	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 19.** 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 20.** 632.865 (2m) of the statutes is created to read:
- 632.865 (2m) FIDUCIARY DUTY AND DISCLOSURES TO HEALTH BENEFIT PLAN SPONSORS. (a) A pharmacy benefit manager owes a fiduciary duty to the health benefit plan sponsor to act according to the health benefit plan sponsor's instructions and in the best interests of the health benefit plan sponsor.
  - (b) A pharmacy benefit manager shall annually provide, no later than the

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- date and using the method prescribed by the commissioner by rule, the health benefit plan sponsor all of the following information from the previous calendar year:
  - 1. The indirect profit received by the pharmacy benefit manager from owning any interest in a pharmacy or service provider.
  - 2. Any payment made by the pharmacy benefit manager to a consultant or broker who works on behalf of the health benefit plan sponsor.
    - 3. From the amounts received from all drug manufacturers, the amounts retained by the pharmacy benefit manager, and not passed through to the health benefit plan sponsor, that are related to the health benefit plan sponsor's claims or bona fide service fees.
    - 4. The amounts, including pharmacy access and audit recovery fees, received from all pharmacies that are in the pharmacy benefit manager's network or have a contract to be in the network and, from these amounts, the amount retained by the pharmacy benefit manager and not passed through to the health benefit plan sponsor.
      - **SECTION 21.** 632.868 of the statutes is created to read:
- 18 **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).
- 22 (c) "Patient assistance program" means a program established by a manufacturer under sub. (3) (a).

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- 1 (d) "Pharmacy" means an entity licensed under s. 450.06 or 450.065.
- 2 (e) "Urgent need of insulin" means having less than a 7-day supply of insulin
  3 readily available for use and needing insulin in order to avoid the likelihood of
  4 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

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- 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

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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.

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- 1 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.

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- 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

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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

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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

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- 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 vear:

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- 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 forfeitures assessed under sub. (9) during the previous calendar year, including the name of the manufacturer and amount of the forfeiture.
  - (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.

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- 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 assistanceprogram.
  - 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

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- 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 fails to comply with this section may be required to forfeit up to \$200,000 per month of noncompliance, with the maximum

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1	forfeiture increasing to \$400,000 per month if the manufacturer continues to be in
2	noncompliance after 6 months and increasing to \$600,000 per month if the
3	manufacturer continues to be in noncompliance after one year.

- **SECTION 22.** 632.869 of the statutes is created to read:
- 6 632.869 Reimbursement to federal drug pricing program
  6 participants. (1) In this section:
  - (a) "Covered entity" means an entity described in 42 USC 256b (a) (4) (A), (D), (E), (J), or (N) that participates in the federal drug pricing program under 42 USC 256b, a pharmacy of the entity, or a pharmacy contracted with the entity to dispense drugs purchased through the federal drug pricing program under 42 USC 256b.
    - (b) "Pharmacy benefit manager" has the meaning given in s. 632.865 (1) (c).
  - (2) No person, including a pharmacy benefit manager or 3rd-party payer, may do any of the following:
  - (a) Reimburse a covered entity for a drug that is subject to an agreement under 42 USC 256b at a rate lower than that paid for the same drug to pharmacies that are not covered entities and have a similar prescription volume to that of the covered entity.
  - (b) Assess a covered entity any fee, charge back, or other adjustment on the basis of the covered entity's participation in the federal drug pricing program under 42 USC 256b.
- **SECTION 23.** 632.895 (6) (title) of the statutes is amended to read:

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1	632.895 <b>(6)</b> (title)	EQUIPMENT AND	SUPPLIES FOR	TREATMENT OF	DIABETES;
2	<u>INSULIN</u> .				

**SECTION 24.** 632.895 (6) of the statutes is renumbered 632.895 (6) (a) and amended to read:

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 25.** 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 policy or 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.

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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 26. Nonstatutory provisions.**

- (1) CENTRALIZED DRUG REPOSITORY. The department of health services shall study and implement a centralized, physical drug repository program under s. 255.056.
- (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.
- (4) OFFICE OF PRESCRIPTION DRUG AFFORDABILITY. The office of the commissioner of insurance shall establish an office of prescription drug affordability in the office of the commissioner of insurance. The office of prescription drug affordability shall be responsible for prescription drug affordability programming within the office of the commissioner of insurance and

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shall oversee the operations of the prescription drug affordability review board established under s. 15.735.

(5) STAGGERED TERMS FOR PRESCRIPTION DRUG AFFORDABILITY REVIEW BOARD. Notwithstanding the length of terms specified for the members of the board under s. 15.735 (1) (b) to (e), 2 of the initial members shall be appointed for terms expiring on May 1, 2026; 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; and 2 of the initial members shall be appointed for terms expiring on May 1, 2029.

## SECTION 27. Fiscal changes.

- (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 2026-27 is increased by \$1,701,000 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 \$1,201,000 to increase the authorized FTE positions for the office of the commissioner of insurance by 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.
- **SECTION 28. Effective dates.** This act takes effect on the day after publication, except as follows:
- (1) 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.

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1 632.895 (6) (b) take effect on the first day of the 4th month beginning after publication.

- (2) PHARMACY BENEFIT TOOL GRANTS. The treatment of ss. 20.005 (3) (schedule), 20.145 (1) (a), and 601.415 (14) takes effect on the day after publication, or on the 2nd day after publication of the 2025 biennial budget act, whichever is later.
- (3) LICENSURE OF PHARMACY SERVICES ADMINISTRATIVE ORGANIZATIONS AND PHARMACEUTICAL REPRESENTATIVES. The treatment of ss. 601.31 (1) (nv) and (nw), 601.56, and 601.57 takes effect on the first day of the 7th month beginning after publication.
- (4) PRESCRIPTION DRUG AFFORDABILITY REVIEW BOARD. The treatment of ss. 15.07 (3) (bm) 7., 15.735, and 20.145 (1) (g) 4. and subch. VI of ch. 601 and SECTIONS 26 (4) and (5) and 27 (1) of this act take effect on the first day of the 7th month beginning after publication or on the 2nd day after publication of the 2025 biennial budget act, whichever is later.

16 (END)