State of Wisconsin
2023 - 2024 LEGISLATURE

LRB-4894/1
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2023 ASSEMBLY BILL 747

December 6, 2023 - Introduced by Representatives SUBECK, C. ANDERSON, J. ANDERSON, ANDRACA, BARE, BILLINGS, CLANCY, CONLEY, CONSIDINE, DRAKE, EMERSON, HONG, JACOBSON, JOERS, MOORE OMOKUNDE, NEUBAUER, ORTIZ-VELEZ, PALMERI, RATCLIFF, SHANKLAND, SHELTON, SINICKI, HAYWOOD and MADISON, cosponsored by Senators PFAFF, HESSELBEIN, AGARD, CARPENTER, L. JOHNSON, LARSON, ROYS, SMITH, SPREITZER, TAYLOR and WIRCH. Referred to Committee on Insurance.

AUTHORS SUBJECT TO CHANGE

AN ACT ***to create*** 15.07 (3) (bm) 7., 15.735, 20.145 (1) (g) 4. and subchapter VI of chapter 601 [precedes 601.78] of the statutes; **relating to:** creating a Prescription Drug Affordability Review Board, funding for an office of prescription drug affordability, crediting certain amounts to the general program operations account of the office of the commissioner of insurance, granting rulemaking authority, and making an appropriation.

Analysis by the Legislative Reference Bureau

This 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 its meetings, make the meeting's materials publicly available

at least one week prior to 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 first step in the reviews is for the board to 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 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.

Further, this bill provides $500,000 in program revenue in fiscal year 2023–24 for onetime implementation costs associated with establishing an Office of Prescription Drug Affordability in the Office of the Commissioner of Insurance. 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 the fiscal biennium 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 administration organizations, and pharmaceutical sales representatives.

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:

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

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

15.735 Same; attached board. (1) There is created a prescription drug affordability review board attached to the office of the commissioner of insurance under s. 15.03. The board shall consist of the following members:

(a) The commissioner of insurance or his or her designee.

(b) Two members appointed for 4–year terms who represent the pharmaceutical drug industry, including pharmaceutical drug manufacturers and wholesalers. At least one of the members appointed under this paragraph shall be a licensed pharmacist.

(c) Two members appointed for 4–year terms who represent the health insurance industry, including insurers and pharmacy benefit managers.

(d) Two members appointed for 4–year terms who represent the health care industry, including hospitals, physicians, pharmacies, and pharmacists. At least one of the members appointed under this paragraph shall be a licensed practitioner.

(e) Two members appointed for 4–year terms who represent the interests of the public.

(2) A member appointed under sub. (1), except for a member appointed under sub. (1) (b), may not be an employee of, a board member of, or a consultant to a drug manufacturer or trade association for drug manufacturers.

(3) Any conflict of interest, including any financial or personal association, that has the potential to bias or has the appearance of biasing an individual's decision in matters related to the board or the conduct of the board's activities shall be considered and disclosed when appointing that individual to the board under sub. (1).

SECTION 3. 20.145 (1) (g) 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 administration organizations, and pharmaceutical sales representatives.

SECTION 4. Subchapter VI of chapter 601 [precedes 601.78] of the statutes is created to read:

CHAPTER 601

SUBCHAPTER VI

PRESCRIPTION DRUG

AFFORDABILITY REVIEW BOARD

601.78 Definitions. In this subchapter:

(1) "Biologic" means a drug that is produced or distributed in accordance with a biologics license application approved under 21 CFR 601.20.

(2) "Biosimilar" means a drug that is produced or distributed in accordance with a biologics license application approved under 42 USC 262 (k) (3).

(3) "Board" means the prescription drug affordability review board established under s. 15.735 (1).

(4) "Brand name drug" means a drug that is produced or distributed in accordance with an original new drug application approved under 21 USC 355 (c), other than an authorized generic drug, as defined in 42 CFR 447.502.

(5) "Financial benefit" includes an honorarium, fee, stock, the value of the stock holdings of a member of the board or any immediate family member, and any direct financial benefit deriving from the finding of a review conducted under s. 601.79.

(6) "Generic drug" means any of the following:

(a) A retail drug that is marketed or distributed in accordance with an abbreviated new drug application approved under 21 USC 355 (j).

(b) An authorized generic drug, as defined in 42 CFR 447.502.

(c) A drug that entered the market prior to 1962 and was not originally marketed under a new drug application.

(7) "Immediate family member" means a spouse, grandparent, parent, sibling, child, stepchild, or grandchild or the spouse of a grandparent, parent, sibling, child, stepchild, or grandchild.

(8) "Manufacturer" means an entity that does all of the following:

(a) Engages in the manufacture of a prescription drug product or enters into a lease with another manufacturer to market and distribute a prescription drug product under the entity's own name.

(b) Sets or changes the wholesale acquisition cost of the prescription drug product described in par. (a).

(9) "Pharmacy benefit manager" has the meaning given in s. 632.865 (1) (c).

(10) "Prescription drug product" means a brand name drug, a generic drug, a biologic, or a biosimilar.

601.785 Prescription drug affordability review board. (1) MISSION. The purpose of the board is to protect state residents, the state, local governments, health plans, health care providers, pharmacies licensed in this state, and other stakeholders of the health care system in this state from the high costs of prescription drug products.

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

1. Meet in open session at least 4 times per year to review prescription drug product pricing information, except that the chair may cancel or postpone a meeting if there is no business to transact.

2. To the extent practicable, access and assess pricing information for prescription drug products by doing all of the following:

a. Accessing and assessing information from other states by entering into memoranda of understanding with other states to which manufacturers report pricing information.

b. Assessing spending for specific prescription drug products in this state.

c. Accessing other available pricing information.

(b) The board may do any of the following:

1. Promulgate rules for the administration of this subchapter.

2. Enter into a contract with an independent 3rd party for any service necessary to carry out the powers and duties of the board. Unless written permission is granted by the board, any person with whom the board contracts may not release, publish, or otherwise use any information to which the person has access under the contract.

(c) The board shall establish and maintain a website to provide public notices and make meeting materials available under sub. (3) (a) and to disclose conflicts of interest under sub. (4) (d).

(3) MEETING REQUIREMENTS. (a) Pursuant to s. 19.84, the board shall provide public notice of each board meeting at least 2 weeks prior to the meeting and shall make the materials for each meeting publicly available at least one week prior to the meeting.

(b) Notwithstanding s. 19.84 (2), the board shall provide an opportunity for public comment at each open meeting and shall provide the public with the opportunity to provide written comments on pending decisions of the board.

(c) Notwithstanding subch. V of ch. 19, any portion of a meeting of the board concerning proprietary data and information shall be conducted in closed session and shall in all respects remain confidential.

(d) The board may allow expert testimony at any meeting, including when the board meets in closed session.

(4) CONFLICTS OF INTEREST. (a) A member of the board shall recuse himself or herself from a decision by the board relating to a prescription drug product if the member or an immediate family member has received or could receive any of the following:

1. A direct financial benefit deriving from a determination, or a finding of a study or review, by the board relating to the prescription drug product.

2. A financial benefit in excess of $5,000 in a calendar year from any person who owns, manufactures, or provides a prescription drug product to be studied or reviewed by the board.

(b) A conflict of interest under this subsection shall be disclosed by the board when hiring board staff, by the appointing authority when appointing members to the board, and by the board when a member of the board is recused from any decision relating to a review of a prescription drug product.

(c) A conflict of interest under this subsection shall be disclosed no later than 5 days after the conflict is identified, except that, if the conflict is identified within 5 days of an open meeting of the board, the conflict shall be disclosed prior to the meeting.

(d) The board shall disclose a conflict of interest under this subsection on the board's website unless the 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 at least 15 percent lower than the referenced brand biologic at the time the biosimilar is launched.

(d) A generic drug that has a wholesale acquisition cost, as adjusted annually to reflect adjustments to the U.S. consumer price index for all urban consumers, U.S. city average, as determined by the U.S. department of labor, that meets all of the following conditions:

1. Is at least $100 for a supply lasting a patient for a period of 30 consecutive days based on the recommended dosage approved for labeling by the federal food and drug administration, a supply lasting a patient for a period of fewer than 30 days based on the recommended dosage approved for labeling by the federal food and drug administration, or one unit of the drug if the labeling approved by the federal food and drug administration does not recommend a finite dosage.

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

(e) Other prescription drug products, including drugs to address public health emergencies, that may create affordability challenges for the health care system and patients in this state.

(2) AFFORDABILITY REVIEW. (a) After identifying prescription drug products under sub. (1), the board shall determine whether to conduct an affordability review for each identified prescription drug product by seeking stakeholder input about the prescription drug product and considering the average patient cost share of the prescription drug product.

(b) The information used to conduct an affordability review under par. (a) may include any document and research related to the manufacturer's selection of the introductory price or price increase of the prescription drug product, including life cycle management, net average price in this state, market competition and context, projected revenue, and the estimated value or cost–effectiveness of the prescription drug product.

(c) The failure of a manufacturer to provide the board with information for an affordability review under par. (b) does not affect the authority of the board to conduct the review.

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

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

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

(c) The total amount of the price concessions, discounts, and rebates the manufacturer provides to each pharmacy benefit manager for the prescription drug product under review, as reported by the manufacturer and pharmacy benefit manager and expressed as a percent of the wholesale acquisition cost.

(d) The price at which therapeutic alternatives to the prescription drug product have been sold in this state.

(e) The average monetary concession, discount, or rebate the manufacturer provides or is expected to provide to health plan payors and pharmacy benefit managers in this state for therapeutic alternatives to the prescription drug product.

(f) The costs to health plans based on patient access consistent with labeled indications by the federal food and drug administration and recognized standard medical practice.

(g) The impact on patient access resulting from the cost of the prescription drug product relative to insurance benefit design.

(h) The current or expected dollar value of drug–specific patient access programs that are supported by the manufacturer.

(i) The relative financial impacts to health, medical, or social services costs that can be quantified and compared to baseline effects of existing therapeutic alternatives to the prescription drug product.

(j) The average patient copay or other cost sharing for the prescription drug product in this state.

(k) Any information a manufacturer chooses to provide.

(L) Any other factors as determined by the board by rule.

(4) UPPER PAYMENT LIMIT. (a) If the board determines under sub. (3) that use of a prescription drug product has led or will lead to an affordability challenge, the board shall establish an upper payment limit for the prescription drug product after considering all of the following:

1. The cost of administering the drug.

2. The cost of delivering the drug to consumers.

3. Other relevant administrative costs related to the drug.

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

(c) 1. The upper payment limit established under this subsection shall apply to all purchases and payor reimbursements of the prescription drug product dispensed or administered to individuals in this state in person, by mail, or by other means.

2. Notwithstanding subd. 1., while state–sponsored and state–regulated health plans and health programs shall limit drug reimbursements and drug payment to no more than the upper payment limit established under this subsection, a plan subject to the Employee Retirement Income Security Act of 1974 or Part D of Medicare under 42 USC 1395w–101 et seq. may choose to reimburse more than the upper payment limit. A provider who dispenses and administers a prescription drug

product in this state to an individual in this state may not bill a payor more than the upper payment limit to the patient regardless of whether a plan subject to the Employee Retirement Income Security Act of 1974 or Part D of Medicare under 42 USC 1395w–101 et seq. chooses to reimburse the provider above the upper payment limit.

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

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

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

SECTION 5. Nonstatutory provisions.

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

(2) STAGGERED TERMS; 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, 2025; 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; and 2 of the initial members shall be appointed for terms expiring on May 1, 2028.

SECTION 6. 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 2024–25 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 authorize 16.0 PR positions within the office of prescription drug affordability, including 5.0 insurance examiners, 4.0 policy initiatives advisors, 2.0 attorneys, 1.0 insurance program manager, 2.0 insurance administrators, and 2.0 operations program associates.

SECTION 7. Effective date.

(1) This act takes effect on the first day of the 7th month beginning after publication.

(END)