Rep. Will Guzzardi

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AMENDMENT TO HOUSE BILL 3493

AMENDMENT NO. _____. Amend House Bill 3493 by replacing everything after the enacting clause with the following:

"Section 1. Short title. This Act may be cited as the Prescription Drug Affordability Act.

Section 5. The General Assembly finds that:

(1) Prescription drugs are an essential part of good health care and a critical component of our health care system. Illinoisans spend $13,000,000,000 each year on prescription drugs and have a vested interest in ensuring they are affordable. People living with chronic conditions need prescription drugs to function and stay healthy. Their quality of life is dependent on them. Access to prescription drugs can be the difference between life and death.

(2) Illinoisans have faced increasing challenges in affording the prescription drugs they depend upon to be

healthy. The costs of brand name drugs have increased 60% since 2014 and annual cost increases regularly outpace medical inflation.

(3) Affordability challenges have led more and more Illinoisans to skip doses of prescribed medication and otherwise ration their medication. An estimated 46,000,000 Americans have skipped or rationed their medications due to cost, sometimes leading to serious medical complications.

(4) The increase in prescription drug costs is the leading driver of increases in health insurance premiums. High prescription drug costs raise State costs under Medicaid and the State Employee Group Insurance Program, raise employer benefits costs, and are passed onto individuals and families.

(5) It is the traditional role of State government to protect the health, safety, and welfare of its residents. Illinois has a long history of ensuring services and products essential to life and health, such as clean water and electricity, are affordable. The State has a compelling reason to ensure prescription drug costs balance consumer access and returns for industry.

(6) The current system is causing affordability challenges for those who depend on insulin. The average cost of insulin tripled from 2002 to 2013, and one out of every 4 individuals living with diabetes has had to ration his or her insulin due to cost. This can lead to serious complications including kidney failure, heart disease, blindness, amputations, and

death.

(7) The current system is causing affordability challenges for those who need prescription drugs to treat multiple sclerosis (MS). Early and ongoing treatment with a disease-modifying therapy for MS is the best way to modify the course of the disease, prevent accumulation of disability, and protect the brain, yet many people cannot access the medications they need. It is estimated that 40% of those living with MS skip doses of medications due to cost. These medications routinely cost $80,000 per year or more and have increased five-fold since they first came to market in the 1990s.

(8) The current system is causing affordability challenges for those who need prescription drugs to treat cancer. Prescriptions to treat cancer routinely cost more than $100,000 per year. The incremental increase in cost for a course of treatment increased from $30,447 in 2006 to $161,141 in 2015. Cancer survivors are 2.7 times more likely to file for bankruptcy than those who have not been diagnosed with cancer.

(9) The current system is causing affordability challenges for those who need prescription drugs to treat rheumatoid arthritis. Medications to treat rheumatoid arthritis increased 70% in only 3 years. The initial cost of rheumatoid arthritis medication was $10,000 per year when it was first introduced, but has increased to $40,000 per year despite several alternatives coming to market.

(10) The State and its residents are facing numerous affordability challenges across many classes of drugs. The current system has not produced affordable costs. An Illinois Prescription Drug Affordability Board that can review multiple classes of drugs across the supply chain is therefore necessary to determine how best to deliver prescription drug costs that are affordable to all Illinoisans.

Section 10. Definitions. In this Act:

"Biologic" means a drug that is produced or distributed in accordance with a biologics license application approved under 42 U.S.C. 447.502.

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

"Board" means the Prescription Drug Affordability Board.

"Brand name drug" means a drug that is produced or distributed in accordance with an original new drug application approved under 21 U.S.C. 355(c). "Brand name drug" does not include an authorized generic drug as defined by 42 CFR 447.502.

"Council" means the Prescription Drug Affordability Stakeholder Council.

"Generic drug" means:

(1) a retail drug that is marketed or distributed in accordance with an abbreviated new drug application,

approved under 21 U.S.C. 355(j);

(2) an authorized generic drug as defined by 42 CFR 447.502; or

(3) a drug that entered the market before 1962 that was not originally marketed under a new drug application.

"Manufacturer" means an entity that:

(1) engages in the manufacture of a prescription drug product; or

(2) enters into a lease with another manufacturer to market and distribute a prescription drug product under the entity's own name; and

(3) sets or changes the wholesale acquisition cost of the prescription drug product it manufactures or markets.

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

Section 15. Prescription Drug Affordability Board.

(a) There is established a Prescription Drug Affordability Board. The purpose of the Board is to protect State residents, State and local governments, commercial health plans, health care providers, pharmacies licensed in the State, and other stakeholders within the health care system from the high costs of prescription drug products. The Board is a public body and is an instrumentality of the State. The Board is an independent unit of State government. The exercise by the Board of its authority under this Act is an essential function.

(b) The 5 members of the Board and 5 alternates shall be appointed by the Governor with the advice and consent of the Senate. The Governor shall select one member to serve as Chair. If the Senate is not in session when the first appointments are made, the Governor shall make temporary appointments as in the case of a vacancy. No Board seat shall remain vacant more than 60 consecutive days.

(c) The Board members and alternates must collectively have expertise in health care economics and clinical medicine. A member or an alternate member may not be an employee of, a board member of, or a consultant to a manufacturer or trade association for manufacturers.

(d) Any conflict of interest, including whether the individual has an association, including a 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 members and alternate members to the Board.

(e) The term of a member or an alternate member is 5 years. The terms of the members and alternate members shall be staggered.

(f) The Chair shall hire an executive director, general counsel, and staff for the Board. Staff of the Board shall receive a salary as provided in the budget of the Board. A member of the Board: (i) may receive compensation as a member

of the Board; and (ii) is entitled to reimbursement for expenses.

(g) A majority of the members of the Board shall constitute a quorum for the purposes of conducting the business of the Board.

(h) Subject to the requirements of this subsection (h), the Board shall meet in open session at least once every 6 weeks to review prescription drug product information. Information concerning the location, date, and time of the meeting must be made publicly available in accordance with the Open Meetings Act. The Chair may cancel or postpone a meeting if there are no prescription drug products to review.

The Board shall perform the following actions in open session: (i) deliberations on whether to subject a prescription drug product to a cost review; (ii) any vote on whether to impose an upper payment limit on purchases and payor reimbursements of prescription drug products in the State; and (iii) any decision by the Board. The Board may otherwise meet in closed session to discuss proprietary data and information.

The Board shall provide public notice of each Board meeting at least 2 weeks in advance of the meeting. Materials for each Board meeting shall be made available to the public at least one week in advance of the meeting. The Board shall provide an opportunity for public comment at each open meeting of the Board. The Board may not make any binding decisions unless this comment period has been provided with a sufficient amount of

time. The Board shall provide the public with the opportunity to provide written comments on pending decisions of the Board. The Board may allow expert testimony at Board meetings, including when the Board meets in closed session.

Members of the Board shall recuse themselves from decisions related to a prescription drug product and disclose interests if the member, or an immediate family member of the member, has received or could receive any of the following: (i) a direct financial benefit of any amount deriving from the result or finding of a study or determination by or for the Board; or (ii) a financial benefit from any person that owns, manufactures, or provides prescription drug products, services, or items to be studied by the Board that in the aggregate exceeds $5,000 per year. A disclosure of interests under this paragraph shall include the type, nature, and magnitude of the interests of the member or his or her immediate family member involved. For the purposes of this paragraph, a financial benefit includes honoraria, fees, stock, the value of the member's or immediate family member's stock holdings, and any direct financial benefit deriving from the finding of a review conducted under this Act.

A conflict of interest shall be disclosed in advance of the first open meeting after the conflict is identified or within 5 days after the conflict is identified. A conflict of interest shall be disclosed by: (i) the Board when hiring Board staff; (ii) the appointing authority when appointing members and

alternate members to the Board and members to the Council; and (iii) the Board when a member of the Board is recused in any final decision resulting from a review of a prescription drug product. A conflict of interest disclosed under this Section shall be posted on the website of the Board unless the Chair of the Board recuses the member from any final decision resulting from a review of a prescription drug product.

Members and alternate members of the Board, Board staff, and third-party contractors may not accept any gift or donation of services or property that indicates a potential conflict of interest or has the appearance of biasing the work of the Board.

Section 20. Powers and duties of the Board.

(a) In furtherance of this Act, the Board shall identify prescription drug products that may create affordability challenges for residents of the State and conduct an affordability review for a minimum of 10 such prescription drug products over the course of a 12-month period. The Board has the authority to set an upper payment limit for such prescription drug products.

(b) To the extent practicable, the Board shall access pricing information for prescription drug products by: (i) entering into a memorandum of understanding with another state to which manufacturers already report pricing information; and (ii) accessing other available pricing information.

(c) In addition to the powers set forth elsewhere in this Act, the Board may: (i) adopt rules for the implementation of this Act; (ii) enter into a contract with a qualified, independent third party for any service necessary to carry out the powers and duties of the Board; and (iii) exercise any and all other powers necessary or desirable to accomplish the purposes, objectives, and provisions of this Act and to perform its duties under this Act. Unless permission is granted by the Board, a third party hired by the Board may not release, publish, or otherwise use any information to which the third party has access under its contract.

Section 25. Prescription Drug Affordability Stakeholder Council.

(a) The Prescription Drug Affordability Stakeholder Council is created.

(b) The purpose of the Council is to provide stakeholder input to assist the Board in making decisions as required under this Act.

(c) The Council shall consist of 25 members appointed 5 each by the Governor, the Speaker of the House of Representatives, the Minority Leader of the House of Representatives, the President of the Senate, and the Minority Leader of the Senate, and shall represent the following entities:

(1) two representative of a statewide health care

advocacy coalition;

(2) one representative of a statewide advocacy organization for seniors;

(3) one representative of a statewide organization for diverse communities;

(4) two representative of a labor union;

(5) two health services researchers specializing in prescription drugs;

(6) one representative of doctors;

(7) one representative of nurses;

(8) one representative of hospitals;

(9) one representative of health insurers;

(10) one representative of the Governor's Office of Management and Budget;

(11) one clinical researcher;

(12) one representative of brand name drug corporations;

(13) one representative of generic drug corporations;

(14) one representative of employers;

(15) one representative of pharmacy benefit managers;

(16) one representative of pharmacists;

(17) one representative of pharmacologists; and

(18) five members of the public.

(d) The members of the Council shall have knowledge of one or more of the following:

(1) the pharmaceutical business model;

(2) supply chain business models;

(3) the practice of medicine or clinical training;

(4) consumer or patient perspectives;

(5) health care costs, trends, and drivers;

(6) clinical and health services research; or

(7) the State's health care marketplace.

(e) From among the membership of the Council, the Board chair shall appoint 2 members to be co-chairs of the Council.

(f) The term of a member is 3 years. The initial members of the Council shall serve staggered terms.

(g) A member of the Council may not receive compensation as a member of the Council, but is entitled to reimbursement for travel expenses.

(h) The Board shall ensure Council membership in accordance with this Section and may deny appointment if appointees do not comply. No Council seat shall remain vacant more than 60 consecutive days.

Section 30. Drug cost affordability review.

(a) The Board shall identify the following prescription drug products and determine whether each identified prescription drug product should be subject to a cost review as described in subsection (e):

(1) brand name drugs and biologics that, as adjusted annually for inflation in accordance with the Consumer Price Index, have:

(A) a launch wholesale acquisition cost of $30,000 or more for a year or course of treatment; or

(B) a wholesale acquisition cost increase of $3,000 or more in any 12-month period, or course of treatment if less than 12 months;

(2) biosimilar drugs that have a launch wholesale acquisition cost that is not at least 15% lower than the referenced brand biologic at the time the biosimilar is launched;

(3) generic drugs that, as adjusted annually for inflation in accordance with the Consumer Price Index, have a wholesale acquisition cost:

(A) of $100 or more for:

(i) a 30-day supply lasting a patient for a period 30 consecutive days based on the recommended dosage approved for labeling by the United States Food and Drug Administration;

(ii) a supply lasting a patient for fewer than 30 days based on the recommended dosage approved for labeling by the United States Food and Drug Administration; or

(iii) one unit of the drug if the labeling approved by the United States Food and Drug Administration does not recommend a finite dosage; and

(B) that increased by 200% or more 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; and

(4) in consultation with the Council, prescription drug products that may create affordability challenges for the State healthcare system, including patients.

(b) After identifying a prescription drug product as required under subsection (a), the Board shall determine whether to conduct a cost review as described in subsection (e) for each identified prescription drug product by:

(1) seeking Council input about the prescription drug product; and

(2) considering the average patient cost share of the prescription drug product.

(c) The information to conduct an affordability review 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 the State, market competition and context, projected revenue, and the estimated value or cost-effectiveness of the prescription drug product.

(d) A manufacturer shall provide such reports as the Board deems necessary for the Board to conduct an affordability review. The Board shall not unreasonably request information that constitutes proprietary, privileged, or confidential

trade secrets under the Freedom of Information Act. Failure of a manufacturer to provide the Board with the information for an affordability review does not affect the authority of the Board to conduct such a review.

(e) If the Board conducts a review of the cost and affordability of a prescription drug product, the review shall determine whether use of the prescription drug product that is fully consistent with the labeling approved by the United States Food and Drug Administration or standard medical practice has led or will lead to affordability challenges for the State health care system or 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 the following factors:

(1) the wholesale acquisition cost for the prescription drug product sold in this State;

(2) the average monetary price concession, discount, or rebate the manufacturer provides to health plans in this State 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;

(3) the total amount of the price concession, discount, or rebate the manufacturer provides to each pharmacy benefit manager operating in this State for the

prescription drug product under review, as reported by manufacturers and pharmacy benefit managers, expressed as a percent of the wholesale acquisition costs;

(4) the price at which therapeutic alternatives have been sold in this State;

(5) 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;

(6) the costs to health plans based on patient access consistent with Federal Food and Drug Administration labeled indications and recognized standard medical practice;

(7) the impact on patient access resulting from the cost of the prescription drug product relative to insurance benefit design;

(8) the current or expected dollar value of drug-specific patient access programs that are supported by the manufacturer;

(9) the relative financial impacts to health, medical, or social services costs as can be quantified and compared to baseline effects of existing therapeutic alternatives;

(10) the average patient co-pay or other cost-sharing for the prescription drug product in this State;

(11) any information a manufacturer chooses to provide; and

(12) any other factors as determined by the Board in rules adopted by the Board.

(f) If the Board finds that the spending on a prescription drug product reviewed under this Section has led or will lead to an affordability challenge, the Board shall establish an upper payment limit after considering: (i) the cost of administering the drug; (ii) the cost of delivering the drug to consumers; and (iii) other relevant administrative costs related to the drug. The upper payment limit applies to all purchases and payor reimbursements of the prescription drug product dispensed or administered to individuals in the State in person, by mail, or by other means.

(g) Any information submitted to the Board in accordance with this Section shall be subject to public inspection only to the extent allowed under the Freedom of Information Act.

(h) This Section may not be construed to prevent a manufacturer from marketing a prescription drug product approved by the United States Food and Drug Administration while the product is under review by the Board.

Section 35. Remedies. The Attorney General shall have authority to enforce this Act. The Attorney General may pursue any available remedy under State or federal law to accomplish the objectives of this Act. Notwithstanding any other provision of law to the contrary, the Board and its staff shall forward any complaints regarding alleged violations of this Act or any

consumer protection law or other law to the Attorney General and work cooperatively with the Attorney General. Nothing in this Section shall be construed to limit the remedies available under State or federal law that provide greater or equal protection to consumers.

Section 40. Appeal of Board decisions.

(a) A person aggrieved by a decision of the Board may request an appeal of the decision within 30 days after the finding of the Board.

(b) The Board shall hear the appeal and make a final decision within 60 days of the hearing.

(c) Any person aggrieved by a final decision of the Board may petition for judicial review.

Section 45. Prescription Drug Affordability Board Fund.

(a) In this Section, "fund" means the Prescription Drug Affordability Board Fund.

(b) The Prescription Drug Affordability Board Fund is created. The fund shall be used only to provide funding for the Board and for the purposes authorized under this Act, including any costs expended by any State agency to implement this Act.

(c) Subject to subsection (g), the Board shall be funded by an assessment on all manufacturers. The Board shall determine the amount of the assessment required under this subsection based on each manufacturer's relative share of gross revenue

from drug sales.

(d) The Board shall pay all moneys collected from the assessment into the fund.

(e) Any investment earnings shall be retained to the credit of the fund.

(f) This Section may not be construed to prohibit the fund from receiving moneys from any other source.

(g) The Board shall be established using general funds, which shall be repaid to the State with the assessments required under subsection (c).

Section 50. Report.

(a) On or before December 31 of each year, the Board shall submit to the General Assembly a report that includes:

(1) price trends for prescription drug products;

(2) the number of prescription drug products that were subject to Board review, including the results of the review and the number and disposition of appeals and judicial reviews of Board decisions; and

(3) any recommendations the Board may have on further legislation needed to make prescription drug products more affordable in this State.

(b) On or before June 1, 2021, the Prescription Drug Affordability Board shall:

(1) conduct a study of the operation of the generic drug market in the United States that includes a review of

physician-administered drugs and considers:

(A) the prices of generic drugs on a year-over-year basis;

(B) the degree to which generic drug prices affect yearly insurance premium changes;

(C) annual changes in insurance cost-sharing for generic drugs;

(D) the potential for and history of drug shortages;

(E) the degree to which generic drug prices affect yearly State Medicaid spending; and

(F) any other relevant study questions; and

(2) report its findings to the General Assembly.

Section 55. Term expiration.

(a) The terms of the initial members and alternate members of the Prescription Drug Affordability Board shall expire as follows:

(1) one member and one alternate member in 2023;

(2) two members and 2 alternate members in 2024; and

(3) two members, including the Chair of the Board, and 2 alternate members in 2025.

(b) The terms of the initial members of the Prescription Drug Affordability Stakeholder Council shall expire as follows:

(1) eight members in 2023;

(2) eight members in 2024; and

(3) nine members in 2025.

Section 60. ERISA plans and Medicare drug plans. This Act obligates State-sponsored and State-regulated health plans and health programs to limit drug reimbursements and drug payment to no more than the Board-established upper payment limit. Employee Retirement Income Security Act (ERISA) plans and Medicare Part D plans are not bound by decisions of the Board and can choose to reimburse more than the upper payment limit. Providers who dispense and administer drugs in this State to individuals in this State are bound to bill all payers no more than the upper payment limit to the patient without regard to whether or not an ERISA plan or Medicare Part D plan chooses to reimburse the provider above the upper payment limit.

Section 97. Severability. If any provision of this Act or the application thereof to any person or circumstance is held invalid for any reason in a court of competent jurisdiction, the invalidity does not affect other provisions or any other application of this Act that can be given effect without the invalid provision or application, and for this purpose the provisions of this Act are declared severable.

Section 900. The State Finance Act is amended by adding Section 5.930 as follows:

(30 ILCS 105/5.930 new)

Sec. 5.930. The Prescription Drug Affordability Board Fund.

Section 999. Effective date. This Act takes effect January 1, 2021.".