AN ACT concerning health.

Be it enacted by the People of the State of Illinois, represented in the General Assembly:

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

Section 5. 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. 1395w-3a(c)(6).

"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.

"Health benefit plan" has the meaning given to that term in Section 513b1 of the Illinois Insurance Code.

"Manufacturer" means an entity that:

(1) owns the patent to 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;

(3) is the labeled entity of the generic product at the point of manufacture; and

(4) 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.

"Wholesale acquisition cost" has the meaning given to that term in 42 U.S.C. 1395w-3a.

Section 10. 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)(1) The 5 members of the Board and 3 alternate members shall be appointed by the Governor with the advice and consent of the Senate.

(2) The Board membership must include individuals with demonstrated expertise in health care economics, pharmaceutical markets, the practice of pharmacy, 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.

(3) 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.

(c) The term of a member or an alternate member is 5 years, except that the terms of the initial members and alternate members shall be staggered as required by the terms provided for members in Section 55. Board members shall be appointed

within 90 days after the effective date of this Act. The Board may begin its work regardless of a delay in appointments to the Prescription Drug Affordability Stakeholder Council created under Section 20.

(d) 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.

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

(f) Subject to the requirements of this subsection, the Board shall meet in open session at least 4 times per year 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 is no business to conduct.

The Board shall perform the following actions in open session: (i) deliberations on whether to subject a prescription drug product to a cost review under subsection (f) of Section 25; and (ii) any vote on whether to impose an upper payment limit on purchases, payments, and payor reimbursements, including reimbursements from health benefit

plans, of prescription drug products in the State. 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 3 weeks in advance of the meeting. Materials for each Board meeting shall be made available to the public at least 3 weeks in advance of the meeting. The Board shall provide an opportunity for public comment at each open meeting of the Board. 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.

(f-5) The Board shall maintain financial records and accounts in accordance with generally accepted governmental accounting principles. The Board shall be deemed a public body for purposes of the Freedom of Information Act and the Open Meetings Act. All records of the Board, including meeting minutes, cost review records, and correspondence, shall be public records subject to disclosure in accordance with the Freedom of Information Act, except as otherwise provided by law. Meetings of the Board shall be open to the public in accordance with the Open Meetings Act.

(g)(1) Members of the Board shall recuse themselves from decisions related to a prescription drug product if the member, or an immediate family member of the member, has received or could receive any of the following:

(A) a direct financial benefit of any amount deriving from the result or finding of a study or determination by or for the Board; or

(B) a financial benefit from any person who 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.

As used in this paragraph, "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.

(2) A disclosure of interests under this Section shall include the type, nature, and magnitude of the interests of the member or the member's immediate family member involved.

(3) 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:

(A) the Board when hiring Board staff;

(B) the appointing authority when appointing members and alternate members to the Board and members to the Council; and

(C) the Board when a member of the Board is recused in any final decision resulting from a review of a prescription drug product.

(4) 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.

(5) 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 15. Powers and duties of the Board. In addition to the powers set forth elsewhere in this Act, the Board may:

(1) adopt rules for the implementation of this Act; and

(2) enter into a contract with a qualified, independent third party for any service necessary to carry out the powers and duties of the Board.

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 20. Prescription Drug Affordability Stakeholder Council.

(a) The Prescription Drug Affordability Stakeholder Council is created. The purpose of the Council is to provide

stakeholder input to assist the Board in making decisions as required under this Act. The Council consists of 15 members appointed within 90 days after the effective date of this Act as follows:

(1) 3 members appointed by the Speaker of the House of Representatives;

(2) 2 members appointed by the Minority Leader of the House of Representatives;

(3) 3 members appointed by the President of the Senate;

(4) 2 members appointed by the Minority Leader of the Senate; and

(5) 5 members appointed by the Governor.

(b) The members of the Council shall have knowledge in 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) clinical and health services research;

(6) the State's health care marketplace;

(7) the practice of community pharmacy; or

(8) the practice of pharmacy administration and expertise in pharmacoeconomics.

(c) From among the membership of the Council, the Board Chair shall appoint one member to be Council Chair.

(d) The term of a member is 3 years, except that the initial members of the Council shall serve staggered terms as required by the terms provided for members in Section 55.

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

Section 21. Operationalization. Before the Board reviews specific drugs for affordability and establishes any upper payment limits, it must establish an operational plan for distribution and access to a drug with an upper payment limit. That operational plan shall address medication availability in the State, pharmacy participation in rural and urban areas, drug distribution in the State, patient access, access to pharmacies in underserved areas, pharmacy deserts, and keystone pharmacies that serve as primary access points for a community.

Section 25. Drug cost affordability review.

(a) The Board shall limit its review of prescription drug products to those that are:

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

(A) a wholesale acquisition cost of $60,000 or more per year or course of treatment if less than a

year; or

(B) a wholesale acquisition cost increase of $3,000 or more in any 12-month period;

(2) biosimilar drugs that have been on the market for at least 3 years, that have a wholesale acquisition cost that is not at least 20% lower than the referenced brand biologic at the time the biosimilars are launched, and that have been suggested for review by members of public, medical professionals, and other stakeholders;

(3) generic drugs that, as adjusted annually for inflation in accordance with the Consumer Price Index, have a wholesale acquisition cost of at least $100 for a 30-day supply or course of treatment less than 30 days and which increased by 200% or more during the immediately 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 immediately preceding 12 months; and

(4) other prescription drug products that may create affordability challenges for the State health care system or patients, including, but not limited to, drugs to address public health emergencies.

The Board shall prioritize establishing and implementing upper payment limits for the 10 prescription drug products with a Medicare Maximum Fair Price that went into effect in 2026 before proceeding with upper payment limits on other

prescription drug products with a Medicare Maximum Fair Price or affordability reviews for any other prescription drug products. Based on the implementation of the upper payment limits, the Board shall make any necessary changes to the operation plan. The Board may establish a maximum of 2 upper payment limits on prescription drug products without a Medicare Maximum Fair Price per calendar year.

The Board is not required to identify every prescription drug that meets the criteria of this subsection.

(b) The Board shall solicit public input on prescription drugs thought to be creating affordability challenges that meet the parameters of paragraphs (1) through (4) of subsection (a). The Board shall determine whether to conduct a full affordability review for the proposed prescription drugs after compiling preliminary information about the cost of the product, patient cost sharing for the product, health plan spending on the product, stakeholder input, and other information decided by the Board.

(c) 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.

(d) The information to conduct an affordability review may include, but is not limited to:

(1) any document and research related to the manufacturer's selection of the introductory price or price increase of the prescription drug product;

(2) any patient assistance program or programs specific to the product;

(3) any estimated or actual manufacturer product price concessions in the market;

(4) any net product cost to State payers;

(5) the relevant factors contributing to the price paid for the prescription drug, including the wholesale acquisition cost, discounts, rebates, or other price concessions;

(6) the average patient copayment or other cost sharing for the drug;

(7) the effect of the price on consumers' access to the drug in the State;

(8) whether the cost of the drug contributes to inequities in the availability of health care to underserved communities in the State;

(9) the price and availability of therapeutic alternatives;

(10) input from any advisory groups established by the Board;

(11) input from patients affected by the condition or

disease treated by the drug and individuals with medical or scientific expertise related to the condition or disease treated by the drug;

(12) life cycle management;

(13) the average cost of the drug in the State;

(14) market competition and context;

(15) projected manufacturer revenue, if available;

(16) off-label usage of the drug; and

(17) any other relevant factors and information as determined by the Board.

(e) 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.

(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 considering exceptional administrative costs related to the distribution of the drug in the State.

(g) The upper payment limit applies to all purchases and payor reimbursements, including reimbursements from health benefit plans, of the prescription drug product intended for use by individuals in the State, in person, by mail, or by other means.

(h) 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.

(i) 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.

(j) Nothing in this Act requires a State department, including, but not limited to, the Department of Healthcare and Family Services, to disclose proprietary information or information prohibited by federal law.

Section 30. Protections and other Board considerations.

(a) The Board shall examine how an upper payment limit would affect a covered entity, as that term is defined in Section 340B of the federal Public Health Service Act.

(b) In determining whether a drug creates an affordability challenge or determining an upper payment limit amount, the Board may not use cost-effectiveness analyses that include the cost-per-quality adjusted life year or a similar measure to identify subpopulations for which a treatment would be less cost-effective due to severity of illness, age, or preexisting disability. In addition, for any treatment that extends life, if the Board uses cost-effectiveness results, the Board must use results that weigh the value of all additional lifetime gained equally for all patients, no matter their severity of illness, age, or preexisting disability.

(c) An upper payment limit is effective no sooner than 6 months after it has been announced. The Board may suspend an

upper payment limit if it determines that there is a shortage of the drug in the State, unless the Board determines that the shortage was caused by a manufacturer or its agent.

(d) State-regulated health plans shall inform the Board of how any upper payment limit-related cost savings are directed to the benefit of enrollees, with a priority on enrollee cost sharing.

(e) The upper payment limit shall not be inclusive of the pharmacy dispensing fee, provider administration fee, or any additional payment amount made by a payor to a provider for the drug product related to the provider's procurement, handling, storage, or other activity facilitating administration of the drug product. The additional payment amount may be reflected in the payor's fee schedule, provider contract, or any other agreement governing reimbursement of the drug product and associated services.

(f) If a prescription drug product subject to an upper payment limit established under this Act is intended to be made available for purchase by pharmacies, distributors, or wholesalers licensed in this State, it shall be available at a price that does not exceed the upper payment limit. If a wholesaler or distributor acquires a prescription drug product subject to an upper payment limit at a price that exceeds the upper payment limit, the wholesaler or distributor is entitled to a chargeback or rebate equal to the difference between the price and the upper payment limit from the entity that sold the

product to the wholesaler or distributor.

(g) No pharmacy shall be required to dispense a prescription drug product subject to an upper payment limit if the product is not reasonably available for purchase at or below the upper payment limit within a time frame consistent with normal pharmacy ordering and delivery practices.

(g-1) Nothing in this Act shall require a pharmacy or dispensing provider to dispense a prescription drug product at a reimbursement rate below the pharmacy's actual acquisition cost plus a reasonable professional dispensing fee.

(g-2) An upper payment limit established under this Act shall apply only to the ingredient cost of a prescription drug product and shall not limit, reduce, or otherwise affect the professional dispensing fee paid to a pharmacy for the safe and lawful dispensing of the medication.

(g-3) A pharmacy benefit manager shall not impose any fee, clawback, reconciliation adjustment, performance adjustment, or other financial assessment that has the effect of reducing reimbursement to a pharmacy below the upper payment limit.

(g-4) Any fee or adjustment that results in reimbursement below the upper payment limit shall constitute a violation of this Act.

(g-5) For purposes of this subsection, "savings" means the difference between the wholesale acquisition cost of a prescription drug product before an upper payment limit and the upper payment limit. All savings shall be applied in the

following order of priority: first, to reduce enrollee cost sharing at the point of sale; second, to reduce premiums; and third, to provide any other direct financial benefit to enrollees.

(g-6) The pharmacy or pharmacist shall not be given the administrative responsibility, either directly or indirectly, of determining patient eligibility, enrollment into plans, etc. Any administrative responsibility of enrolling patients into a plan or providing coverage must be done through enrollment in a State-managed health benefit plan.

(h) The Board shall not create an upper payment limit that is different from the Medicare Maximum Fair Price for the prescription drug product that has a Medicare Maximum Fair Price.

(i) An upper payment limit shall be implemented no sooner than the Medicare implementation date and shall not be subject to the requirements of Section 25.

(j) Medicare Part C and D plans are not required to reimburse at the upper payment limit.

(k) Any upper payment limit established by the Board shall not apply to prescription drug products purchased by the Department of Healthcare and Family Services for the medical assistance program under Article V of the Illinois Public Aid Code or to a health care plan serving Medicaid populations that provides, arranges for, pays for, or reimburses the cost of any health care service for persons who are enrolled under

the medical assistance program under Article V of the Illinois Public Aid Code unless, after consultation with and approval of the Director of Healthcare and Family Services, it is determined that the upper payment limit would reduce costs to the State.

(l) Any upper payment limit established by the Board shall not apply to prescription drug products purchased or reimbursed by the Department of Central Management Services in conjunction with its administration of the State Employees Group Insurance Program or any health care plan established or maintained under the State Employee Group Insurance Act of 1971 unless, after consultation with and approval of the Director of the Department of Central Management Services, it is determined that the upper payment limit would reduce costs to the State.

Section 35. Remedies. The Attorney General may enforce this Act. The Attorney General may pursue any available remedy under State law when enforcing this Act.

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 after the appeal is requested.

(c) Any person aggrieved by a final decision of the Board may petition for judicial review in accordance with the provisions of the Administrative Review Law.

Section 45. Prescription Drug Affordability Board Fund. The Prescription Drug Affordability Board Fund is created as a special fund in the State treasury. The Board shall be funded by an annual assessment on all manufacturers whose products are sold in the State. The total annual assessment shall be set at the amount necessary to fund Board operations, not to exceed $750,000 in any fiscal year, and shall be apportioned equally among all manufacturers in the assessed class. A manufacturer that does not sell drug products in the State must submit a written statement to the Board certifying that no drug product manufactured or distributed by that manufacturer was sold in the State during the preceding fiscal year to be exempt from the assessment. The Board shall collect the annual assessment in accordance with rules adopted by the Board. The rules shall specify the methodology and timeline for collecting the assessment. All funds collected by the Board from the assessments shall be deposited into the Fund. 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. All interest earned on moneys in the Fund shall be credited to the Fund. This Section may not be construed to prohibit the Fund

from receiving moneys from any other source that does not create the appearance of a conflict of interest. The Board shall be established using general funds, which shall be repaid to the State with the assessments required under this Section. The Board may not spend more than $750,000 annually and funds that are not used in one fiscal year shall roll over to the following fiscal year.

Section 50. Reports.

(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, 2027, the Board shall submit a report to the General Assembly about the operation of the generic drug market in the United States that includes a review of physician-administered drugs and considers:

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

(2) the degree to which generic drug prices affect

insurance premiums as reported by health insurers in this State or other states that collect this information;

(3) recent and current trends in patient cost sharing for generic drugs;

(4) the causes and prevalence of generic drug shortages; and

(5) any other relevant study questions.

(c) The Board shall notify the General Assembly if 5 years have passed without any litigation hindering Board operations.

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 2029;

(2) 2 members and one alternate member in 2030; and

(3) 2 members, including the Chair of the Board, and one alternate member in 2031.

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

(1) 5 members in 2029;

(2) 5 members in 2030; and

(3) 5 members in 2031.

Section 90. Repeal. This Act is repealed 5 years after the

effective date of this Act.

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 5.1038 as follows:

(30 ILCS 105/5.1038 new)

Sec. 5.1038. The Prescription Drug Affordability Board Fund. This Section is repealed 5 years after the effective date of this amendatory Act of the 104th General Assembly.

Section 999. Effective date. This Act takes effect 180 days after becoming law.