Rep. Nabeela Syed

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AMENDMENT TO HOUSE BILL 4472

AMENDMENT NO. _____. Amend House Bill 4472 by replacing everything after the enacting clause with the following:

"Section 1. Short title. This Act may be cited as the Health Care Availability and Access 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. 262(k)(3).

"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 Health Care Availability and Access 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 Health Care Availability and Access 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) 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.

Section 10. Health Care Availability and Access Board.

(a) There is established a Health Care Availability and Access 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, 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 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, including a financial or personal association, 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. Initial Board members shall be appointed within 4 months after the effective date of this Act. The Board may begin its work if there is a delay in appointments to the Health Care Availability and Access 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, except as otherwise provided in this Section. 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 affordability 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 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.

(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 in an aggregate amount that exceeds $5,000 per year from any person who owns, manufactures, or provides prescription drug products,

services, or items to be studied by the Board.

A disclosure of interests under this paragraph shall include the type, nature, and magnitude of the interests of the member or the member's immediate family member.

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 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.

(3) 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.

(4) 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. Health Care Availability and Access Stakeholder Council.

(a) The Health Care Availability and Access 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 4 months 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.

(A) 2 members appointed by the Governor shall represent health care providers;

(B) 2 members appointed by the Governor shall represent patients and health care consumers; and

(C) One member appointed by the Governor shall be a patient living with a rare disease or a current or former caregiver of a patient living with a rare disease.

(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; or

(6) the State's health care marketplace.

(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 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 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 the 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 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, research and development costs of the manufacturer for the drug and the extent to which the manufacturer has recouped research and development costs, 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 in a manner 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, any document and research related to the manufacturer's selection of the introductory price or price increase of the prescription drug product, patient assistance program or programs specific to the product, estimated or actual manufacturer product price concessions in the market, net product cost to State payers, and other 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 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.

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, directly or indirectly through a contracted entity or other third party, 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.

(d) Any savings generated by a health plan as a result of

an upper payment limit established by the Board shall be used to reduce costs to consumers, prioritizing the reduction of out-of-pocket costs for prescription drugs. Each health plan shall submit to the Board an annual report describing the savings achieved as a result of implementing upper payment limits and how those savings were used to reduce costs to consumers.

(e) The upper payment limit shall not be inclusive of the pharmacy dispensing fee, provider administration fee, or add-on fee for provider-administered drugs.

(f) State licensed independent pharmacies may not be reimbursed less than the upper payment limit.

(g) The Board shall adopt the Medicare Maximum Fair Price as defined in 42 U.S.C. 1320f(c)(3) for a prescription drug as the upper payment limit for that prescription drug product intended for use by individuals in this State, per subsection (g) of Section 25.

Section 35. Remedies. The Attorney General shall have authority to 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 of the hearing.

(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. Health Care Availability and Access Board Fund. The Health Care Availability and Access Board Fund is created as a special fund in the State treasury. The Board shall be funded by an annual assessment it assesses on all manufacturers whose products are sold in the State. 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.

Section 50. Reports.

(a) On or before December 31 of each year, the Board shall submit to the General Assembly in accordance with Section 3.1

of the General Assembly Organization Act 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;

(3) for each medication affected, the patient impact of any upper payment limits that have been established and in effect for more than 12 months before the report is published; and

(4) 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, 2025, the Health Care Availability and Access Board shall submit a report to the General Assembly concerning 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.

Section 55. Term expiration.

(a) The terms of the initial members and alternate members of the Health Care Availability and Access Board shall expire as follows:

(1) one member and one alternate member in 2028;

(2) 2 members and one alternate member in 2029; and

(3) 2 members, including the Chair of the Board, and one alternate member in 2030.

(b) The terms of the initial members of the Health Care Availability and Access Stakeholder Council shall expire as follows:

(1) 5 members in 2028;

(2) 5 members in 2029; and

(3) 5 members in 2030.

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 5.1015 as follows:

(30 ILCS 105/5.1015 new)

Sec. 5.1015. The Health Care Availability and Access Board Fund.

Section 999. Effective date. This Act takes effect upon becoming law.".