



Rep. Nabeela Syed

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LRB104 06394 BAB 36181 a

1 AMENDMENT TO HOUSE BILL 1443

2 AMENDMENT NO. \_\_\_\_\_. Amend House Bill 1443 by replacing  
3 everything after the enacting clause with the following:

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

6 Section 5. Definitions. In this Act:

7 "Biologic" means a drug that is produced or distributed in  
8 accordance with a biologics license application approved under  
9 42 U.S.C. 1395w-3a(c)(6).

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

13 "Board" means the Prescription Drug Affordability Board.

14 "Brand name drug" means a drug that is produced or  
15 distributed in accordance with an original new drug  
16 application approved under 21 U.S.C. 355(c). "Brand name drug"

1 does not include an authorized generic drug as defined by 42  
2 CFR 447.502.

3 "Council" means the Prescription Drug Affordability  
4 Stakeholder Council.

5 "Generic drug" means:

6 (1) a retail drug that is marketed or distributed in  
7 accordance with an abbreviated new drug application,  
8 approved under 21 U.S.C. 355(j);

9 (2) an authorized generic drug as defined by 42 CFR  
10 447.502; or

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

13 "Manufacturer" means an entity that:

14 (1) owns the patent to a prescription drug product; or

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

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

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

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

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

26 "Wholesale acquisition cost" has the meaning given to that

1 term in 42 U.S.C. 1395w-3a.

2 Section 10. Prescription Drug Affordability Board.

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

13 (b) (1) The 5 members of the Board and 3 alternate members  
14 shall be appointed by the Governor with the advice and consent  
15 of the Senate.

16 (2) The Board membership must include individuals with  
17 demonstrated expertise in health care economics,  
18 pharmaceutical markets, the practice of pharmacy, and clinical  
19 medicine. A member or an alternate member may not be an  
20 employee of, a Board member of, or a consultant to a  
21 manufacturer or trade association for manufacturers.

22 (3) Any conflict of interest, including whether the  
23 individual has an association, including a financial or  
24 personal association, that has the potential to bias or has  
25 the appearance of biasing an individual's decision in matters

1 related to the Board or the conduct of the Board's activities,  
2 shall be considered and disclosed when appointing members and  
3 alternate members to the Board.

4 (c) The term of a member or an alternate member is 5 years,  
5 except that the terms of the initial members and alternate  
6 members shall be staggered as required by the terms provided  
7 for members in Section 55. Board members shall be appointed  
8 within 90 days after the effective date of this Act. The Board  
9 may begin its work regardless of a delay in appointments to the  
10 Prescription Drug Affordability Stakeholder Council created  
11 under Section 20.

12 (d) The Chair shall hire an executive director, general  
13 counsel, and staff for the Board. Staff of the Board shall  
14 receive a salary as provided in the budget of the Board. A  
15 member of the Board: (i) may receive compensation as a member  
16 of the Board; and (ii) is entitled to reimbursement for  
17 expenses.

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

21 (f) Subject to the requirements of this subsection, the  
22 Board shall meet in open session at least 4 times per year to  
23 review prescription drug product information. Information  
24 concerning the location, date, and time of the meeting must be  
25 made publicly available in accordance with the Open Meetings  
26 Act. The Chair may cancel or postpone a meeting if there is no

1 business to conduct.

2 The Board shall perform the following actions in open  
3 session: (i) deliberations on whether to subject a  
4 prescription drug product to a cost review under subsection  
5 (f) of Section 25; and (ii) any vote on whether to impose an  
6 upper payment limit on purchases, payments, and payor  
7 reimbursements, including reimbursements from health benefit  
8 plans, of prescription drug products in the State. The Board  
9 may otherwise meet in closed session to discuss proprietary  
10 data and information.

11 The Board shall provide public notice of each Board  
12 meeting at least 3 weeks in advance of the meeting. Materials  
13 for each Board meeting shall be made available to the public at  
14 least 3 weeks in advance of the meeting. The Board shall  
15 provide an opportunity for public comment at each open meeting  
16 of the Board. The Board shall provide the public with the  
17 opportunity to provide written comments on pending decisions  
18 of the Board. The Board may allow expert testimony at Board  
19 meetings, including when the Board meets in closed session.

20 (f-5) The Board shall maintain financial records and  
21 accounts in accordance with generally accepted governmental  
22 accounting principles. The Board shall be deemed a public body  
23 for purposes of the Freedom of Information Act and the Open  
24 Meetings Act. All records of the Board, including meeting  
25 minutes, cost review records, and correspondence, shall be  
26 public records subject to disclosure in accordance with the

1 Freedom of Information Act, except as otherwise provided by  
2 law. Meetings of the Board shall be open to the public in  
3 accordance with the Open Meetings Act.

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

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

11 (B) a financial benefit from any person who owns,  
12 manufactures, or provides prescription drug products,  
13 services, or items to be studied by the Board that in the  
14 aggregate exceeds \$5,000 per year.

15 As used in this paragraph, "financial benefit" includes  
16 honoraria, fees, stock, the value of the member's or immediate  
17 family member's stock holdings, and any direct financial  
18 benefit deriving from the finding of a review conducted under  
19 this Act.

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

23 (3) A conflict of interest shall be disclosed in advance  
24 of the first open meeting after the conflict is identified or  
25 within 5 days after the conflict is identified. A conflict of  
26 interest shall be disclosed by:

1 (A) the Board when hiring Board staff;

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

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

8 (4) A conflict of interest disclosed under this Section  
9 shall be posted on the website of the Board unless the Chair of  
10 the Board recuses the member from any final decision resulting  
11 from a review of a prescription drug product.

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

17 Section 15. Powers and duties of the Board. In addition to  
18 the powers set forth elsewhere in this Act, the Board may:

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

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

24 Unless permission is granted by the Board, a third party  
25 hired by the Board may not release, publish, or otherwise use

1 any information to which the third party has access under its  
2 contract.

3 Section 20. Prescription Drug Affordability Stakeholder  
4 Council.

5 (a) The Prescription Drug Affordability Stakeholder  
6 Council is created. The purpose of the Council is to provide  
7 stakeholder input to assist the Board in making decisions as  
8 required under this Act. The Council consists of 15 members  
9 appointed within 90 days after the effective date of this Act  
10 as follows:

11 (1) 3 members appointed by the Speaker of the House of  
12 Representatives;

13 (2) 2 members appointed by the Minority Leader of the  
14 House of Representatives;

15 (3) 3 members appointed by the President of the  
16 Senate;

17 (4) 2 members appointed by the Minority Leader of the  
18 Senate; and

19 (5) 5 members appointed by the Governor.

20 (b) The members of the Council shall have knowledge in one  
21 or more of the following:

22 (1) the pharmaceutical business model;

23 (2) supply chain business models;

24 (3) the practice of medicine or clinical training;

25 (4) consumer or patient perspectives;

- 1           (5) clinical and health services research;  
2           (6) the State's health care marketplace;  
3           (7) the practice of community pharmacy; or  
4           (8) the practice of pharmacy administration and  
5 expertise in pharmacoeconomics.

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

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

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

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

24           Section 25. Drug cost affordability review.

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

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

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

9 (B) a wholesale acquisition cost increase of  
10 \$3,000 or more in any 12-month period;

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

17 (3) generic drugs that, as adjusted annually for  
18 inflation in accordance with the Consumer Price Index,  
19 have a wholesale acquisition cost of at least \$100 for a  
20 30-day supply or course of treatment less than 30 days and  
21 which increased by 200% or more during the immediately  
22 preceding 12-month period, as determined by the difference  
23 between the resulting wholesale acquisition cost and the  
24 average of the wholesale acquisition cost reported over  
25 the immediately preceding 12 months; and

26 (4) other prescription drug products that may create

1           affordability challenges for the State health care system  
2           or patients, including, but not limited to, drugs to  
3           address public health emergencies.

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

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

15          (c) If the Board conducts a review of the cost and  
16          affordability of a prescription drug product, the review shall  
17          determine whether use of the prescription drug product that is  
18          fully consistent with the labeling approved by the United  
19          States Food and Drug Administration or standard medical  
20          practice has led or will lead to affordability challenges for  
21          the State health care system or high out-of-pocket costs for  
22          patients.

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

25                  (1) any document and research related to the  
26                  manufacturer's selection of the introductory price or

1 price increase of the prescription drug product;

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

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

6 (4) any net product cost to State payers;

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

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

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

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

18 (9) the price and availability of therapeutic  
19 alternatives;

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

22 (11) input from patients affected by the condition or  
23 disease treated by the drug and individuals with medical  
24 or scientific expertise related to the condition or  
25 disease treated by the drug;

26 (12) life cycle management;

1           (13) the average cost of the drug in the State;  
2           (14) market competition and context;  
3           (15) projected manufacturer revenue, if available;  
4           (16) off-label usage of the drug; and  
5           (17) any other relevant factors and information as  
6           determined by the Board.

7           (e) Failure of a manufacturer to provide the Board with  
8           the information for an affordability review does not affect  
9           the authority of the Board to conduct such a review.

10          (f) If the Board finds that the spending on a prescription  
11          drug product reviewed under this Section has led or will lead  
12          to an affordability challenge, the Board shall establish an  
13          upper payment limit considering exceptional administrative  
14          costs related to the distribution of the drug in the State.

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

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

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

1 Section 30. Protections and other Board considerations.

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

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

16 (c) An upper payment limit is effective no sooner than 6  
17 months after it has been announced. The Board may suspend an  
18 upper payment limit if it determines that there is a shortage  
19 of the drug in the State, unless the Board determines that the  
20 shortage was caused by a manufacturer or its agent.

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

25 (e) The upper payment limit shall not be inclusive of the

1 pharmacy dispensing fee, provider administration fee, or any  
2 additional payment amount made by a payor to a provider for the  
3 drug product related to the provider's procurement, handling,  
4 storage, or other activity facilitating administration of the  
5 drug product. The additional payment amount may be reflected  
6 in the payor's fee schedule, provider contract, or any other  
7 agreement governing reimbursement of the drug product and  
8 associated services.

9 (f) A wholesaler or distributor shall make any  
10 prescription drug product that is subject to an upper payment  
11 limit established under this Act available for purchase by  
12 pharmacies licensed in this State at a price that does not  
13 exceed the established upper payment limit.

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

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

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

1 and lawful dispensing of the medication.

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

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

9 (g-5) For purposes of this subsection, "savings" means the  
10 difference between the wholesale acquisition cost of a  
11 prescription drug product and the upper payment limit. All  
12 savings shall be applied in the following order of priority:  
13 first, to reduce enrollee cost sharing at the point of sale;  
14 second, to reduce premiums; and third, to provide any other  
15 direct financial benefit to enrollees.

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

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

26 (i) The Board shall implement an upper payment limit that

1 is the same as the Medicare Maximum Fair Price no sooner than  
2 the Medicare implementation date.

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

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

9 (l) Any upper payment limit established by the Board shall  
10 not apply to prescription drug products purchased by the  
11 Department of Healthcare and Family Services for the medical  
12 assistance program under Article V of the Illinois Public Aid  
13 Code unless, after consultation with and approval of the  
14 Director of Healthcare and Family Services, it is determined  
15 that the upper payment limit would reduce costs to the State.

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

19 Section 40. Appeal of Board decisions.

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

23 (b) The Board shall hear the appeal and make a final  
24 decision within 60 days after the appeal is requested.

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

4 Section 45. Prescription Drug Affordability Board Fund.  
5 The Prescription Drug Affordability Board Fund is created as a  
6 special fund in the State treasury. The Board shall be funded  
7 by an annual assessment on all manufacturers whose products  
8 are sold in the State. All funds collected by the Board from  
9 the assessments shall be deposited into the Fund. The Fund  
10 shall be used only to provide funding for the Board and for the  
11 purposes authorized under this Act, including any costs  
12 expended by any State agency to implement this Act. All  
13 interest earned on moneys in the Fund shall be credited to the  
14 Fund. This Section may not be construed to prohibit the Fund  
15 from receiving moneys from any other source that does not  
16 create the appearance of a conflict of interest. The Board  
17 shall be established using general funds, which shall be  
18 repaid to the State with the assessments required under this  
19 Section.

20 Section 50. Reports.

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

- 23 (1) price trends for prescription drug products;  
24 (2) the number of prescription drug products that were

1 subject to Board review, including the results of the  
2 review and the number and disposition of appeals and  
3 judicial reviews of Board decisions; and

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

7 (b) On or before June 1, 2027, the Board shall submit a  
8 report to the General Assembly about the operation of the  
9 generic drug market in the United States that includes a  
10 review of physician-administered drugs and considers:

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

13 (2) the degree to which generic drug prices affect  
14 insurance premiums as reported by health insurers in this  
15 State or other states that collect this information;

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

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

20 (5) any other relevant study questions.

21 Section 55. Term expiration.

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

25 (1) one member and one alternate member in 2029;

1 (2) 2 members and one alternate member in 2030; and

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

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

7 (1) 5 members in 2029;

8 (2) 5 members in 2030; and

9 (3) 5 members in 2031.

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

17 Section 900. The State Finance Act is amended by adding  
18 Section 5.1038 as follows:

19 (30 ILCS 105/5.1038 new)

20 Sec. 5.1038. The Prescription Drug Affordability Board  
21 Fund.

22 Section 999. Effective date. This Act takes effect 180

1 days after becoming law.".