



Rep. Nabeela Syed

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1 AMENDMENT TO SENATE BILL 3496

2 AMENDMENT NO. _____. Amend Senate Bill 3496 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 "Health benefit plan" has the meaning given to that term
14 in Section 513b1 of the Illinois Insurance Code.

15 "Manufacturer" means an entity that:

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

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

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

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

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 shall prioritize establishing and implementing
5 upper payment limits for the 10 prescription drug products
6 with a Medicare Maximum Fair Price that went into effect in
7 2026 before proceeding with upper payment limits on other
8 prescription drug products with a Medicare Maximum Fair Price
9 or affordability reviews for any other prescription drug
10 products. Based on the implementation of the upper payment
11 limits, the Board shall make any necessary changes to the
12 operation plan. The Board may establish a maximum of 2 upper
13 payment limits on prescription drug products without a
14 Medicare Maximum Fair Price per calendar year.

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

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

26 (c) If the Board conducts a review of the cost and

1 affordability of a prescription drug product, the review shall
2 determine whether use of the prescription drug product that is
3 fully consistent with the labeling approved by the United
4 States Food and Drug Administration or standard medical
5 practice has led or will lead to affordability challenges for
6 the State health care system or high out-of-pocket costs for
7 patients.

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

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

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

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

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

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

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

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

26 (8) whether the cost of the drug contributes to

1 inequities in the availability of health care to
2 underserved communities in the State;

3 (9) the price and availability of therapeutic
4 alternatives;

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

7 (11) input from patients affected by the condition or
8 disease treated by the drug and individuals with medical
9 or scientific expertise related to the condition or
10 disease treated by the drug;

11 (12) life cycle management;

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

13 (14) market competition and context;

14 (15) projected manufacturer revenue, if available;

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

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

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

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

26 (g) The upper payment limit applies to all purchases and

1 payor reimbursements, including reimbursements from health
2 benefit plans, of the prescription drug product intended for
3 use by individuals in the State, in person, by mail, or by
4 other means.

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

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

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

16 Section 30. Protections and other Board considerations.

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

20 (b) In determining whether a drug creates an affordability
21 challenge or determining an upper payment limit amount, the
22 Board may not use cost-effectiveness analyses that include the
23 cost-per-quality adjusted life year or a similar measure to
24 identify subpopulations for which a treatment would be less
25 cost-effective due to severity of illness, age, or preexisting

1 disability. In addition, for any treatment that extends life,
2 if the Board uses cost-effectiveness results, the Board must
3 use results that weigh the value of all additional lifetime
4 gained equally for all patients, no matter their severity of
5 illness, age, or preexisting disability.

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

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

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

24 (f) If a prescription drug product subject to an upper
25 payment limit established under this Act is intended to be
26 made available for purchase by pharmacies, distributors, or

1 wholesalers licensed in this State, it shall be available at a
2 price that does not exceed the upper payment limit. If a
3 wholesaler or distributor acquires a prescription drug product
4 subject to an upper payment limit at a price that exceeds the
5 upper payment limit, the wholesaler or distributor is entitled
6 to a chargeback or rebate equal to the difference between the
7 price and the upper payment limit from the entity that sold the
8 product to the wholesaler or distributor.

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

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

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

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

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

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

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

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

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

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

1 (k) Any upper payment limit established by the Board shall
2 not apply to prescription drug products purchased by the
3 Department of Healthcare and Family Services for the medical
4 assistance program under Article V of the Illinois Public Aid
5 Code or to a health care plan serving Medicaid populations
6 that provides, arranges for, pays for, or reimburses the cost
7 of any health care service for persons who are enrolled under
8 the medical assistance program under Article V of the Illinois
9 Public Aid Code unless, after consultation with and approval
10 of the Director of Healthcare and Family Services, it is
11 determined that the upper payment limit would reduce costs to
12 the State.

13 (1) Any upper payment limit established by the Board shall
14 not apply to prescription drug products purchased or
15 reimbursed by the Department of Central Management Services in
16 conjunction with its administration of the State Employees
17 Group Insurance Program or any health care plan established or
18 maintained under the State Employee Group Insurance Act of
19 1971 unless, after consultation with and approval of the
20 Director of the Department of Central Management Services, it
21 is determined that the upper payment limit would reduce costs
22 to the State.

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

1 Section 40. Appeal of Board decisions.

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

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

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

10 Section 45. Prescription Drug Affordability Board Fund.
11 The Prescription Drug Affordability Board Fund is created as a
12 special fund in the State treasury. The Board shall be funded
13 by an annual assessment on all manufacturers whose products
14 are sold in the State. The total annual assessment shall be set
15 at the amount necessary to fund Board operations, not to
16 exceed \$750,000 in any fiscal year, and shall be apportioned
17 equally among all manufacturers in the assessed class. A
18 manufacturer that does not sell drug products in the State
19 must submit a written statement to the Board certifying that
20 no drug product manufactured or distributed by that
21 manufacturer was sold in the State during the preceding fiscal
22 year to be exempt from the assessment. The Board shall collect
23 the annual assessment in accordance with rules adopted by the
24 Board. The rules shall specify the methodology and timeline

1 for collecting the assessment. All funds collected by the
2 Board from the assessments shall be deposited into the Fund.
3 The Fund shall be used only to provide funding for the Board
4 and for the purposes authorized under this Act, including any
5 costs expended by any State agency to implement this Act. All
6 interest earned on moneys in the Fund shall be credited to the
7 Fund. This Section may not be construed to prohibit the Fund
8 from receiving moneys from any other source that does not
9 create the appearance of a conflict of interest. The Board
10 shall be established using general funds, which shall be
11 repaid to the State with the assessments required under this
12 Section. The Board may not spend more than \$750,000 annually
13 and funds that are not used in one fiscal year shall roll over
14 to the following fiscal year.

15 Section 50. Reports.

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

18 (1) price trends for prescription drug products;

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

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

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

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

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

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

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

14 (5) any other relevant study questions.

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

17 Section 55. Term expiration.

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

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

22 (2) 2 members and one alternate member in 2030; and

23 (3) 2 members, including the Chair of the Board, and
24 one alternate member in 2031.

25 (b) The terms of the initial members of the Prescription

1 Drug Affordability Stakeholder Council shall expire as
2 follows:

- 3 (1) 5 members in 2029;
4 (2) 5 members in 2030; and
5 (3) 5 members in 2031.

6 Section 90. Repeal. This Act is repealed 5 years after the
7 effective date of this Act.

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

15 Section 900. The State Finance Act is amended by adding
16 Section 5.1038 as follows:

17 (30 ILCS 105/5.1038 new)

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

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

1 days after becoming law.".