



Sen. Graciela Guzmán

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LRB104 07474 BAB 35203 a

1 AMENDMENT TO SENATE BILL 66

2 AMENDMENT NO. _____. Amend Senate Bill 66 by replacing
3 everything after the enacting clause with the following:

4 "Section 1. Short title. This Act may be cited as the
5 Health Care Availability and Access 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 Health Care Availability and Access
14 Board.

15 "Brand name drug" means a drug that is produced or
16 distributed in accordance with an original new drug

1 application approved under 21 U.S.C. 355(c). "Brand name drug"
2 does not include an authorized generic drug as defined by 42
3 CFR 447.502.

4 "Council" means the Health Care Availability and Access
5 Stakeholder Council.

6 "Generic drug" means:

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

10 (2) an authorized generic drug as defined by 42 CFR
11 447.502; or

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

14 "Manufacturer" means an entity that:

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

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

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

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

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

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

1 Section 10. Health Care Availability and Access Board.

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

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

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

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

1 shall be considered and disclosed when appointing members and
2 alternate members to the Board.

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

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

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

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

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

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

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

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

26 (B) a financial benefit from any person who owns,

1 manufactures, or provides prescription drug products,
2 services, or items to be studied by the Board that in the
3 aggregate exceeds \$5,000 per year.

4 As used in this paragraph, "financial benefit" includes
5 honoraria, fees, stock, the value of the member's or immediate
6 family member's stock holdings, and any direct financial
7 benefit deriving from the finding of a review conducted under
8 this Act.

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

12 (3) A conflict of interest shall be disclosed in advance
13 of the first open meeting after the conflict is identified or
14 within 5 days after the conflict is identified. A conflict of
15 interest shall be disclosed by:

16 (A) the Board when hiring Board staff;

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

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

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

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

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

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

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

13 Unless permission is granted by the Board, a third party
14 hired by the Board may not release, publish, or otherwise use
15 any information to which the third party has access under its
16 contract.

17 Section 20. Health Care Availability and Access
18 Stakeholder Council.

19 (a) The Health Care Availability and Access Stakeholder
20 Council is created. The purpose of the Council is to provide
21 stakeholder input to assist the Board in making decisions as
22 required under this Act. The Council consists of 15 members
23 appointed within 90 days after the effective date of this Act
24 as follows:

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

3 (2) 2 members appointed by the Minority Leader of the
4 House of Representatives;

5 (3) 3 members appointed by the President of the
6 Senate;

7 (4) 2 members appointed by the Minority Leader of the
8 Senate; and

9 (5) 5 members appointed by the Governor.

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

12 (1) the pharmaceutical business model;

13 (2) supply chain business models;

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

15 (4) consumer or patient perspectives;

16 (5) clinical and health services research; or

17 (6) the State's health care marketplace.

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

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

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

1 Section 25. Drug cost affordability review.

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

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

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

10 (B) a wholesale acquisition cost increase of
11 \$3,000 or more in any 12-month period;

12 (2) biosimilar drugs that have a wholesale acquisition
13 cost that is not at least 20% lower than the referenced
14 brand biologic at the time the biosimilars are launched,
15 and that have been suggested for review by members of
16 public, 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 or provider administration fee.

2 (f) State licensed independent pharmacies may not be
3 reimbursed less than the upper payment limit, including
4 reimbursements from health benefit plans.

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

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

14 (i) The Board shall implement an upper payment limit that
15 is the same as the Medicare Maximum Fair Price no sooner than
16 the Medicare implementation date.

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

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

23 (l) Any upper payment limit established by the Board shall
24 not apply to prescription drug products purchased by the
25 Department of Healthcare and Family Services for the medical
26 assistance program under Article V of the Illinois Public Aid

1 Code unless, after consultation with and approval of the
2 Director of Healthcare and Family Services, it is determined
3 that the upper payment limit would reduce costs to the State.

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

7 Section 40. Appeal of Board decisions.

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

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

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

16 Section 45. Health Care Availability and Access Board
17 Fund. The Health Care Availability and Access Board Fund is
18 created as a special fund in the State treasury. The Board
19 shall be funded by an annual assessment on all manufacturers
20 whose products are sold in the State. All funds collected by
21 the Board from the assessments shall be deposited into the
22 Fund. The Fund shall be used only to provide funding for the
23 Board and for the purposes authorized under this Act,

1 including any costs expended by any State agency to implement
2 this Act. All interest earned on moneys in the Fund shall be
3 credited to the Fund. This Section may not be construed to
4 prohibit the Fund from receiving moneys from any other source
5 that does not create the appearance of a conflict of interest.
6 The Board shall be established using general funds, which
7 shall be repaid to the State with the assessments required
8 under this Section.

9 Section 50. Reports.

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

- 12 (1) price trends for prescription drug products;
- 13 (2) the number of prescription drug products that were
14 subject to Board review, including the results of the
15 review and the number and disposition of appeals and
16 judicial reviews of Board decisions; and
- 17 (3) any recommendations the Board may have on further
18 legislation needed to make prescription drug products more
19 affordable in this State.

20 (b) On or before June 1, 2025, the Health Care
21 Availability and Access Board shall submit a report to the
22 General Assembly about the operation of the generic drug
23 market in the United States that includes a review of
24 physician-administered drugs and considers:

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

1 basis;

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

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

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

9 (5) any other relevant study questions.

10 Section 55. Term expiration.

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

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

15 (2) 2 members and one alternate member in 2030; and

16 (3) 2 members, including the Chair of the Board, and
17 one alternate member in 2031.

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

21 (1) 5 members in 2029;

22 (2) 5 members in 2030; and

23 (3) 5 members in 2031.

24 Section 97. Severability. If any provision of this Act or

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

7 Section 900. The State Finance Act is amended by adding
8 Section 5.1038 as follows:

9 (30 ILCS 105/5.1038 new)

10 Sec. 5.1038. The Health Care Availability and Access Board
11 Fund.

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