



## 103RD GENERAL ASSEMBLY

### State of Illinois

2023 and 2024

SB3108

Introduced 2/2/2024, by Sen. David Koehler

#### SYNOPSIS AS INTRODUCED:

New Act  
30 ILCS 105/5.1015 new

Creates the Health Care Availability and Access Board Act. Establishes the Health Care Availability and Access Board 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. Contains provisions concerning Board membership and terms; staff for the Board; Board meetings; circumstances under which Board members must recuse themselves; and other matters. Provides that the Board shall perform the following actions in open session: (i) deliberations on whether to subject a prescription drug product to a cost review; 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. Permits the Board to adopt rules to implement the Act and to enter into a contract with a qualified, independent third party for any service necessary to carry out the powers and duties of the Board. Creates the Health Care Availability and Access Stakeholder Council to provide stakeholder input to assist the Board in making decisions as required by the Act. Contains provisions concerning Council membership, member terms, and other matters. Provides that the Board shall adopt the federal Medicare Maximum Fair Price as the upper payment limit for a prescription drug product intended for use by individuals in the State. Requires the Attorney General to enforce the Act. Effective 180 days after becoming law.

LRB103 39220 CES 69370 b

1 AN ACT concerning health.

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

4 Section 1. Short title. This Act may be cited as the Health  
5 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. 447.502.

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

20 "Council" means the Health Care Availability and Access  
21 Stakeholder Council.

22 "Generic drug" means:

23 (1) a retail drug that is marketed or distributed in

1           accordance with an abbreviated new drug application,  
2           approved under 21 U.S.C. 355(j);

3           (2) an authorized generic drug as defined by 42 CFR  
4           447.502; or

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

7           "Manufacturer" means an entity that:

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

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

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

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

16          "Prescription drug product" means a brand name drug, a  
17          generic drug, a biologic, or a biosimilar.

18          Section 10. Health Care Availability and Access Board.

19          (a) There is established a Health Care Availability and  
20          Access Board. The purpose of the Board is to protect State  
21          residents, State and local governments, commercial health  
22          plans, health care providers, pharmacies licensed in the  
23          State, and other stakeholders within the health care system  
24          from the high costs of prescription drug products. The Board  
25          is a public body and is an instrumentality of the State. The

1 Board is an independent unit of State government. The exercise  
2 by the Board of its authority under this Act is an essential  
3 function.

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

7 (2) The Board membership must include individuals with  
8 demonstrated expertise in health care economics,  
9 pharmaceutical market, and clinical medicine. A member or an  
10 alternate member may not be an employee of, a Board member of,  
11 or a consultant to a manufacturer or trade association for  
12 manufacturers.

13 (3) Any conflict of interest, including whether the  
14 individual has an association, including a financial or  
15 personal association, that has the potential to bias or has  
16 the appearance of biasing an individual's decision in matters  
17 related to the Board or the conduct of the Board's activities,  
18 shall be considered and disclosed when appointing members and  
19 alternate members to the Board.

20 (c) The term of a member or an alternate member is 5 years,  
21 except that the terms of the initial members and alternate  
22 members shall be staggered as required by the terms provided  
23 for members in Section 55. Initial Board members shall be  
24 appointed within 4 months after the effective date of this  
25 Act. The Board may begin its work if there is a delay in  
26 appointments to the Health Care Availability and Access

1 Stakeholder Council created under Section 20.

2 (d) The Chair shall hire an executive director, general  
3 counsel, and staff for the Board. Staff of the Board shall  
4 receive a salary as provided in the budget of the Board. A  
5 member of the Board: (i) may receive compensation as a member  
6 of the Board; and (ii) is entitled to reimbursement for  
7 expenses.

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

11 (f) Subject to the requirements of this subsection, the  
12 Board shall meet in open session at least 4 times per year to  
13 review prescription drug product information. Information  
14 concerning the location, date, and time of the meeting must be  
15 made publicly available in accordance with the Open Meetings  
16 Act. The Chair may cancel or postpone a meeting if there are no  
17 prescription drug products to review.

18 The Board shall perform the following actions in open  
19 session: (i) deliberations on whether to subject a  
20 prescription drug product to a cost review under subsection  
21 (f) of Section 25; and (ii) any vote on whether to impose an  
22 upper payment limit on purchases, payments, and payor  
23 reimbursements of prescription drug products in the State. The  
24 Board may otherwise meet in closed session to discuss  
25 proprietary data and information.

26 The Board shall provide public notice of each Board

1 meeting at least 3 weeks in advance of the meeting. Materials  
2 for each Board meeting shall be made available to the public at  
3 least 3 weeks in advance of the meeting. The Board shall  
4 provide an opportunity for public comment at each open meeting  
5 of the Board. The Board shall provide the public with the  
6 opportunity to provide written comments on pending decisions  
7 of the Board. The Board may allow expert testimony at Board  
8 meetings, including when the Board meets in closed session.

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

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

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

20 A disclosure of interests under this paragraph shall  
21 include the type, nature, and magnitude of the interests of  
22 the member or his or her immediate family member involved.

23 For the purposes of this paragraph, "financial benefit"  
24 includes honoraria, fees, stock, the value of the member's or  
25 immediate family member's stock holdings, and any direct  
26 financial benefit deriving from the finding of a review

1 conducted under this Act.

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

6 (A) the Board when hiring Board staff;

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

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

13 (3) A conflict of interest disclosed under this Section  
14 shall be posted on the website of the Board unless the Chair of  
15 the Board recuses the member from any final decision resulting  
16 from a review of a prescription drug product.

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

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

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

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

4           Unless permission is granted by the Board, a third party  
5           hired by the Board may not release, publish, or otherwise use  
6           any information to which the third party has access under its  
7           contract.

8           Section 20. Health Care Availability and Access  
9           Stakeholder Council.

10          (a) The Health Care Availability and Access Stakeholder  
11          Council is created. The purpose of the Council is to provide  
12          stakeholder input to assist the Board in making decisions as  
13          required under this Act. The Council consists of 15 members  
14          appointed within 4 months after the effective date of this Act  
15          as follows:

16                (1) 3 members appointed by the Speaker of the House of  
17                Representatives;

18                (2) 2 members appointed by the Minority Leader of the  
19                House of Representatives;

20                (3) 3 members appointed by the President of the  
21                Senate;

22                (4) 2 members appointed by the Minority Leader of the  
23                Senate; and

24                (5) 5 members appointed by the Governor.

25          (b) The members of the Council shall have knowledge in one



1 or more of the following:

- 2 (1) the pharmaceutical business model;
- 3 (2) supply chain business models;
- 4 (3) the practice of medicine or clinical training;
- 5 (4) consumer or patient perspectives;
- 6 (5) clinical and health services research; or
- 7 (6) the State's health care marketplace.

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

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

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

16 Section 25. Drug cost affordability review.

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

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

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

25 (B) a wholesale acquisition cost increase of

1           \$3,000 or more in any 12-month period;

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

7           (3) generic drugs that, as adjusted annually for  
8           inflation in accordance with the Consumer Price Index,  
9           have a wholesale acquisition cost of at least \$100 for a  
10          30-day supply or course of treatment less than 30 days and  
11          which increased by 200% or more during the immediately  
12          preceding 12-month period, as determined by the difference  
13          between the resulting wholesale acquisition cost and the  
14          average of the wholesale acquisition cost reported over  
15          the immediately preceding 12 months; and

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

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

23          (b) The Board shall solicit public input on prescription  
24          drugs thought to be creating affordability challenges that  
25          meet the parameters of paragraphs (1) through (4) of  
26          subsection (a). The Board shall determine whether to conduct a

1 full affordability review for the proposed prescription drugs  
2 after compiling preliminary information about the cost of the  
3 product, patient cost sharing for the product, health plan  
4 spending on the product, stakeholder input, and other  
5 information decided by the Board.

6 (c) If the Board conducts a review of the cost and  
7 affordability of a prescription drug product, the review shall  
8 determine whether use of the prescription drug product that is  
9 fully consistent with the labeling approved by the United  
10 States Food and Drug Administration or standard medical  
11 practice has led or will lead to affordability challenges for  
12 the State health care system or high out-of-pocket costs for  
13 patients.

14 (d) The information to conduct an affordability review may  
15 include, but is not limited to, any document and research  
16 related to the manufacturer's selection of the introductory  
17 price or price increase of the prescription drug product,  
18 patient assistance program or programs specific to the  
19 product, estimated or actual manufacturer product price  
20 concessions in the market, net product cost to State payers,  
21 and other information as determined by the Board.

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

25 (f) If the Board finds that the spending on a prescription  
26 drug product reviewed under this Section has led or will lead

1 to an affordability challenge, the Board shall establish an  
2 upper payment limit considering exceptional administrative  
3 costs related to the distribution of the drug in the State.

4 (g) The upper payment limit applies to all purchases and  
5 payor reimbursements of the prescription drug product intended  
6 for use by individuals in the State, in person, by mail, or by  
7 other means.

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

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

15 Section 30. Protections and other Board considerations.

16 (a) The Board shall examine how an upper payment limit  
17 would affect 340B providers.

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

1 use results that weigh the value of all additional lifetime  
2 gained equally for all patients no matter their severity of  
3 illness, age, or preexisting disability.

4 (c) An upper payment limit is effective no sooner than 6  
5 months after it has been announced.

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

10 (e) The upper payment limit shall not be inclusive of the  
11 pharmacy dispensing fee or provider administration fee.

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

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

19 Section 35. Remedies. The Attorney General shall have  
20 authority to enforce this Act. The Attorney General may pursue  
21 any available remedy under State law when enforcing this Act.

22 Section 40. Appeal of Board decisions.

23 (a) A person aggrieved by a decision of the Board may  
24 request an appeal of the decision within 30 days after the

1 finding of the Board.

2 (b) The Board shall hear the appeal and make a final  
3 decision within 60 days of the hearing.

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

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

23 Section 50. Reports.

24 (a) On or before December 31 of each year, the Board shall

1 submit to the General Assembly a report that includes:

2 (1) price trends for prescription drug products;

3 (2) the number of prescription drug products that were  
4 subject to Board review, including the results of the  
5 review and the number and disposition of appeals and  
6 judicial reviews of Board decisions; and

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

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

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

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

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

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

24 (5) any other relevant study questions.

25 Section 55. Term expiration.

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

- 4 (1) one member and one alternate member in 2028;  
5 (2) 2 members and one alternate member in 2029; and  
6 (3) 2 members, including the Chair of the Board, and  
7 one alternate member in 2030.

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

- 11 (1) 5 members in 2028;  
12 (2) 5 members in 2029; and  
13 (3) 5 members in 2030.

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

21 Section 900. The State Finance Act is amended by adding  
22 Section 5.1015 as follows:

23 (30 ILCS 105/5.1015 new)



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

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