



Sen. David Koehler

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10400HB4327sam001

LRB104 17027 BAB 38647 a

1 AMENDMENT TO HOUSE BILL 4327

2 AMENDMENT NO. _____. Amend House Bill 4327 by replacing
3 everything after the enacting clause with the following:

4 "Section 1. Short title. This Act may be cited as the 340B
5 Transparency, Reporting, and Accountability Act.

6 Section 5. Findings. The General Assembly finds that:

7 (1) The intent of the 340B Drug Discount Program is to
8 provide resources to reach more eligible patients and
9 provide more comprehensive services. In doing so, 340B
10 covered entities provide discounted medicines to eligible
11 health care organizations for the purpose of improving
12 access to affordable medications and health care services
13 for low-income, underinsured, uninsured, or otherwise
14 vulnerable patients being treated at eligible hospitals,
15 clinics, federally qualified health centers (FQHC), and
16 safety-net hospitals in or adjacent to vulnerable

1 communities.

2 (2) Congress intended the 340B Drug Discount Program
3 to provide discounts to 340B covered entities that provide
4 direct health care to uninsured and underinsured
5 vulnerable patients.

6 (3) The appropriate and effective use of the 340B Drug
7 Discount Program is essential for improving health
8 outcomes, particularly for vulnerable and underserved
9 communities in rural, suburban, and urban areas throughout
10 Illinois meeting the definitions of vulnerable
11 communities.

12 (4) There is a need for statewide data to evaluate the
13 ways in which 340B Drug Discount Program utilization,
14 financial impact, and patient benefits enable vulnerable
15 Illinoisans to access care and fit into the overall health
16 care safety net framework. Additional transparency in
17 aggregate financial and operational reporting enhances
18 legislative oversight without interfering with federal
19 law. Increased transparency is needed to ensure that
20 vulnerable communities receive the benefits intended from
21 the Patient Access to Pharmacy Protection Act.

22 (5) To protect vulnerable communities, the General
23 Assembly must pass the Health Equity Infrastructure Access
24 and Stabilization Act. This includes creation of and
25 funding of the following components:

26 (A) the Vulnerable Community Health Capital Fund

1 Voluntary investment program;

2 (B) the Community Health Networks of Continuum
3 Care;

4 (C) the Illinois Safety Net Hospital Package;

5 (D) the Behavioral and Mental Health (BMH) Access
6 and Expansion Fund;

7 (E) the Stabilization and Sustainability
8 Operational Funding Program;

9 (F) the 340B Grantee Contract Pharmacy Access Act
10 integration;

11 (G) sustainable funding opportunities through
12 transparency of the 340B Federal Program; and

13 (H) the Unified Health Equity Omnibus Package.

14 (6) Savings associated with the federal 340B Drug
15 Discount Program may support the financial stability of
16 hospitals, FQHCs, Ryan White providers, rural providers,
17 and other historical safety-net institutions serving
18 vulnerable communities experiencing health care access
19 shortages, provider scarcity, or risk of service reduction
20 or closure.

21 (7) Vulnerable communities in the State of Illinois
22 are populations or geographic areas whose residents
23 experience disproportionate barriers to achieving optimal
24 health outcomes due to cumulative social, economic,
25 environmental, and structural disadvantages. These
26 communities are characterized by elevated health

1 disparities, limited access to health care services, and
2 increased exposure to risk factors, such as poverty,
3 inadequate insurance coverage, geographic isolation,
4 systemic discrimination, and unmet social determinants of
5 health, including housing, transportation, food security,
6 and environmental conditions, and who, as a result of
7 these conditions, experience reduced access to timely,
8 culturally competent, and geographically proximate
9 community-based hospital and health care services.

10 (8) This Act is intended solely to establish a
11 State-level reporting and transparency framework to allow
12 the 340B program to be evaluated, and shall not regulate
13 pricing, reimbursement, or participation in the federal
14 340B Program.

15 Section 10. Definitions. As used in this Act:

16 "340B covered entity" or "covered entity" means an entity
17 in Illinois that qualifies as a covered entity under Section
18 340B of the federal Public Health Service Act, 42 U.S.C.
19 256b(a)(4).

20 "340B Drug Discount Program" means the program established
21 under Section 340B of the federal Public Health Service Act,
22 42 U.S.C. 256b.

23 "340B entity type" means the designation of the 340B
24 covered entity according to the entity types specified in 42
25 U.S.C. 256b(a)(4).

1 "340B identification number" means the unique
2 identification number provided by the Health Resources and
3 Services Administration to identify a 340B-eligible entity in
4 the 340B Office of Pharmacy Affairs Information System.

5 "340B contract pharmacy" means any pharmacy that is under
6 contract with a 340B covered entity to dispense 340B drugs on
7 behalf of the 340B covered entity and is either (i) located in
8 Illinois and qualifies as a pharmacy under Section 3 of the
9 Pharmacy Practice Act; or (ii) is located in a state,
10 commonwealth, or territory of the United States, other than
11 Illinois, and dispenses 340B drugs on behalf of the 340B
12 covered entity.

13 "340B grantee" means an entity in Illinois that qualifies
14 as a covered entity under subparagraphs (A)-(K) of paragraph
15 (4) of subsection (a) of Section 340B of the federal Public
16 Health Service Act, 42 U.S.C. 256b(a)(4)(A)-(K).

17 "Critical Access Hospital" has the meaning given to that
18 term in paragraph (4) of subsection (b) of Section 5-5e of the
19 Illinois Public Aid Code.

20 "Hospital" means a hospital licensed under the Hospital
21 Licensing Act or University of Illinois Hospital Act.

22 "Pharmaceutical manufacturer" has the meaning given to the
23 term "manufacturer" in the Wholesale Drug Distribution
24 Licensing Act.

25 "Reporting year" means the 12-month period to be covered
26 by the report described in Section 15, as determined by the

1 Department of Insurance.

2 "Safety-Net Hospital" has the meaning given to that term
3 Section 5-5e.1 of the Illinois Public Aid Code.

4 "Vulnerable communities" include, but are not limited to:

5 (1) low-income and economically disadvantaged
6 populations, including households below 80% of area median
7 income;

8 (2) racial and ethnic minority populations and
9 historically marginalized groups experiencing systemic
10 inequities;

11 (3) rural and medically underserved areas with limited
12 provider access or hospital closures;

13 (4) communities facing environmental justice burdens,
14 including high pollution exposure;

15 (5) populations with higher prevalence of chronic
16 disease and poor health outcomes linked to social
17 determinants of health; or

18 (6) individuals with disabilities, older adults,
19 LGBTQ+ populations, and justice-involved individuals
20 identified as equity-focused populations under Illinois
21 law.

22 Section 15. 340B Drug Discount Program study.

23 (a) As soon as practical after the effective date of this
24 Act, the Department of Insurance shall conduct a comprehensive
25 study of how 340B covered entities and pharmaceutical

1 manufacturers within Illinois participate in the 340B Drug
2 Discount Program. The study shall include an examination of
3 the impact of this participation by 340B covered entities on
4 State health programs, such as Medicaid and the State
5 Employees Group Insurance Program. The study shall include,
6 but not be limited to, an assessment of:

7 (1) with respect to each covered entity, the:

8 (A) name;

9 (B) service address;

10 (C) 340B identification number; and

11 (D) 340B designation, as specified in 42 U.S.C
12 256b(a)(4);

13 (2) the aggregate amount, by 340B entity type, spent
14 on third-party administrators for the management of the
15 340B Drug Discount Program;

16 (3) the average difference between the cost imposed by
17 each covered entity on 340B-priced drugs and the
18 reimbursement rate for 340B drugs, organized by
19 therapeutic class;

20 (4) the aggregate and transaction-level acquisition
21 cost paid by a 340B covered entity for all prescription
22 drugs organized by therapeutic class obtained under the
23 340B Drug Discount Program and dispensed or administered
24 to patients;

25 (5) the aggregate and transaction-level payment amount
26 received by a 340B covered entity for all drugs organized

1 by therapeutic class obtained under the 340B Drug Discount
2 Program and dispensed or administered to patients;

3 (6) with respect to 340B covered entities, a list of
4 contract pharmacies contracted with the 340B covered
5 entity to dispense 340B covered drugs;

6 (7) the aggregate and transaction-level payment made
7 to contract pharmacies to dispense drugs obtained under
8 the 340B Drug Discount Program;

9 (8) how the 340B covered entity uses any savings from
10 participating in the 340B Drug Discount Program, including
11 the total amount of 340B savings used for the provision of
12 charity care, community benefits (including identification
13 of the benefit program), any similar program of providing
14 unreimbursed or subsidized health care, and any remaining
15 savings for other purposes;

16 (9) to the extent the information is available, the
17 percentage of total patients of the 340B covered entity
18 that were:

19 (A) served by a sliding fee scale for a
20 prescription drug dispensed or administered under the
21 340B Drug Discount Program;

22 (B) Medicaid customers and uninsured or
23 underinsured patients;

24 (C) racial and ethnic minority populations;

25 (D) patients residing in rural or Medically
26 Underserved Areas, including Governor's Exceptions,

1 designated by the Health Resources and Services
2 Administration, an agency of the United States
3 Department of Health and Human Services;

4 (E) populations with a higher prevalence of
5 chronic disease and poor health outcomes linked to
6 societal determinants of health; and

7 (F) individuals with disabilities, older adults,
8 LGBTQ+ populations, and justice-involved individuals;

9 (10) with respect to covered entities, the 340B
10 covered entity's total operating costs;

11 (11) with respect to covered entities, a copy of the
12 340B covered entity's financial assistance policy for the
13 reporting year;

14 (12) identification of the parties involved in the
15 340B procurement and dispensing process for each covered
16 facility;

17 (13) the aggregate and transaction-level payment made
18 to a pharmacy services administrative organization that
19 provides pharmacy services for a 340B contract pharmacy;

20 (14) the aggregate and transaction-level payment made
21 to a pharmacy benefit manager that provides pharmacy
22 benefit management services for a 340B covered entity, if
23 the information has not already been submitted in a
24 pharmaceutical manufacturer 340B audit;

25 (15) the total cost and number of hours spent
26 preparing the data in response to the study;

1 (16) with respect to pharmaceutical manufacturers,
2 copies of any 340B audits conducted during the previous
3 calendar year;

4 (17) the specific pharmaceutical manufacturers that
5 are participating in the 340B Drug Discount Program in
6 Illinois;

7 (18) with respect to pharmaceutical manufacturers, any
8 restrictions placed by that manufacturer on participation
9 in the 340B Drug Discount Program, any accompanying data
10 supporting those restrictions, and the reasoning;

11 (19) a description of the impact of the 340B Drug
12 Discount Program on the patients and the community served
13 by each 340B covered entity;

14 (20) with respect to pharmaceutical manufacturers, and
15 for the purpose of analyzing the impact of the 340B Drug
16 Discount Program, the aggregate amount of all 340B
17 discounts provided for each calendar year beginning in
18 2020; and

19 (21) with respect to pharmaceutical manufacturers, the
20 aggregate amount of all 340B discounts provided for each
21 calendar year beginning in 2020, stated as a percentage of
22 the manufacturer's total annual revenues.

23 (b) The Department of Insurance may adopt rules as
24 necessary to implement this Section.

25 (c) The Department of Insurance shall request the
26 information described in subsection (a) in a format designated

1 by the Department. All 340B covered entities, and
2 pharmaceutical manufacturers doing business in the State of
3 Illinois, shall comply with requests for information relevant
4 to subsection (a) from the Department of Insurance in the
5 format prescribed and within the timeframe specified. Failure
6 by a covered entity or pharmaceutical manufacturer to submit
7 all requested information described in subsection (a) within
8 30 calendar days from the time frame specified by the
9 Department shall result in a fine levied by the Director of:
10 (1) \$500 per day the information is past due; or (2) \$100 per
11 day the information is past due for hospitals with fewer than
12 100 licensed beds, Critical Access Hospitals, Safety-Net
13 Hospitals, and 340B grantees. Fines collected pursuant to this
14 subsection shall be deposited into the Vulnerable Community
15 Hospital Capital Investment Fund, which is hereby created as a
16 special fund in the State treasury. All moneys in the
17 Vulnerable Community Hospital Capital Investment Fund shall be
18 used to support the health equity framework for supporting
19 access to health care, creating sustainability, and supporting
20 the implementation of the 340B Drug Discount Program. The
21 Department of Insurance shall enforce this Section pursuant to
22 the powers granted to it by law, including, but not limited to,
23 the powers provided under Article XXIV of the Illinois
24 Insurance Code. Subsections (2) through (5) of Section 403A of
25 the Illinois Insurance Code shall apply to the imposition of
26 any fine.

1 (d) Subject to subsection (e), the Department of Insurance
2 shall maintain the confidentiality of any information
3 submitted under subsection (c) for which the submitting person
4 or entity includes a request that meets the criteria in
5 paragraph (g) of subsection (1) of Section 7 of the Freedom of
6 Information Act, and the information shall not be subject to
7 subpoena in any private civil litigation in this State.
8 Nothing in this Section shall prevent the Department of
9 Insurance from furnishing information collected from 340B
10 covered entities or pharmaceutical manufacturers to State or
11 federal authorities that may investigate, prosecute, or pursue
12 other legal action against a 340B covered entity or
13 pharmaceutical manufacturer for violations of 42 U.S.C. 256b
14 or any applicable State law.

15 (e) The Department of Insurance shall submit a report of
16 the findings of its study to the General Assembly and to the
17 Governor by July 1, 2028. The report shall provide findings
18 aggregated across 340B covered entities and pharmaceutical
19 manufacturers and shall not disclose information or data
20 attributed to any specific 340B covered entity or
21 pharmaceutical manufacturer. The report shall note any
22 requests for information from the Department of Insurance
23 where the requested information was never submitted. The
24 report shall address whether the data collected by the
25 Department indicates a need for annual or biennial reporting
26 by 340B covered entities. The report may include any

1 aggregated findings related to the populations identified in
2 paragraph (9) of subsection (a). The report shall address
3 whether the data collected by the Department indicates a need
4 for biennial reporting by 340B covered entities.

5 Section 20. Severability. If any provision of this Act or
6 the Patient Access to Pharmacy Act is held invalid by a court,
7 the validity of the remainder of this Act and the Patient
8 Access to Pharmacy Act shall not be affected by that
9 determination of invalidity. If the applicability of any
10 provision of this Act or the Patient Access to Pharmacy Act to
11 any person or circumstance is held invalid by a court, the
12 applicability of that provision to other persons or
13 circumstances shall not be affected by that determination of
14 invalidity.

15 Section 95. Repeal. This Act is repealed on July 1, 2032.

16 Section 900. If and only if House Bill 2371 of the 104th
17 General Assembly becomes law, then the Patient Access to
18 Pharmacy Protection Act is amended by changing Section 40 and
19 Section 99 as follows:

20 (10400HB2371sam002, Sec. 40)

21 Sec. 40. Enforcement.

22 (a) The Attorney General is authorized to enforce this Act

1 ~~under its general authority under the Attorney General Act. If~~
2 the Attorney General has reasonable cause to believe that
3 there is or has been a violation of Section 15 of this Act,
4 then the Attorney General may commence a civil action in the
5 name of the People of the State of Illinois to enforce the
6 provisions of this Act in the appropriate circuit court.

7 (b) Upon finding a violation of Section 15 of this Act, a
8 court may order:

9 (1) temporary, preliminary, or permanent injunctive
10 relief for any act, policy, or practice that violates this
11 Act;

12 (2) money damages to be paid to the 340B covered
13 entity as a result of the violation of this Act;

14 (3) the assessment of a civil penalty of up to \$1,000
15 per violation for each violation of Section 15; or

16 (4) any other relief.

17 (c) A civil penalty imposed or a settlement or other
18 payment made pursuant to this Act shall be made payable to the
19 Attorney General's State Projects and Court Ordered
20 Distribution Fund.

21 (Source: 10400HB2371sam002.)

22 (10400HB2371sam002, Sec. 99)

23 Sec. 99. Effective date. This Act takes effect upon
24 becoming law or on the effective date of House Bill 4327 of the
25 104th General Assembly, whichever is later; however, this Act

1 does not take effect at all unless House Bill 4327 of the 104th
2 General Assembly becomes law.

3 (Source: 10400HB2371sam002.)

4 Section 905. The State Finance Act is amended by adding
5 Section 5.1038 as follows:

6 (30 ILCS 105/5.1038 new)

7 Sec. 5.1038. The Vulnerable Community Hospital Capital
8 Investment Fund.

9 Section 999. Effective date. This Act takes effect upon
10 becoming law or on the effective date of House Bill 2371 of the
11 104th General Assembly, as amended by Senate Amendment No. 2,
12 whichever is later; however, this Act does not take effect at
13 all unless House Bill 2371 of the 104th General Assembly, as
14 amended by Senate Amendment No. 2, becomes law.".