



Rep. Camille Y. Lilly

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10400HB4327ham002

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1 AMENDMENT TO HOUSE BILL 4327

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

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

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

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

1 safety-net hospitals in or adjacent to vulnerable
2 communities.

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

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

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

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

1 (A) the Vulnerable Community Health Capital Fund
2 Voluntary investment program;

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

5 (C) the Illinois Safety Net Hospital Package;

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

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

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

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

14 (H) the Unified Health Equity Omnibus Package.

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

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

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

11 (8) This Act is intended solely to establish a
12 state-level reporting and transparency framework to allow
13 the 340B program to be evaluated, and shall not regulate
14 pricing, reimbursement, or participation in the federal
15 340B Program.

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

17 "340B covered entity" or "covered entity" means a covered
18 entity as defined in 42 U.S.C. 256b(a)(4), with a service
19 address in Illinois as of January 1 of the reporting year.

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, and as stated in Section 10 of the Patient
23 Access to Pharmacy Protection Act.

24 "340B entity type" means the designation of the 340B
25 covered entity according to the entity types specified in 42

1 U.S.C. 256b(a)(4), and as stated in Section 10 of the Patient
2 Access to Pharmacy Protection Act.

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

7 "340B contract pharmacy" means a pharmacy that enters into
8 a contract with a 340B covered entity to provide services to
9 the 340B covered entity's patients, including dispensing
10 entity-owned 340B drugs, and as stated in Section 10 of the
11 Patient Access to Pharmacy Protection Act.

12 "Reporting year" means the 12-month period to be covered
13 by the report described in Section 15, as determined by the
14 Department of Insurance.

15 "Pharmaceutical manufacturer" means an entity that is
16 engaged in:

17 (1) the production, preparation, propagation,
18 compounding, conversion, or processing of prescription
19 drug products, either directly or indirectly by extraction
20 from substances of natural origin, independently by means
21 of chemical synthesis, or by a combination of extraction
22 and chemical synthesis; or

23 (2) the packaging, repackaging, labeling, relabeling,
24 or distribution of prescription drug products.

25 "Pharmaceutical manufacturer" does not include a wholesale
26 distributor of drugs or a retail pharmacy licensed under State

1 law.

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

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

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

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

11 (4) communities facing environmental justice burdens,
12 including high pollution exposure;

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

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

20 Section 15. 340B Drug Discount Program study.

21 (a) As soon as practical after the effective date of this
22 Act, the Department of Insurance shall conduct a comprehensive
23 study of how 340B covered entities and pharmaceutical
24 manufacturers within Illinois participate in the 340B Drug
25 Discount Program. The study shall include an examination of

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

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

6 (A) name;

7 (B) service address;

8 (C) 340B identification number; and

9 (D) 340B designation, as specified in 42 U.S.C
10 256b(a)(4);

11 (2) with respect to covered entities, the aggregate
12 amount, by 340B entity type, of 340B revenue, defined as
13 the total patient and payer reimbursement less the total
14 340B acquisition cost, generated by 340B covered entities
15 from both self-administered and physician-administered
16 drugs;

17 (3) the aggregate amount, by 340B entity type, spent
18 on third-party administrators for the management of the
19 340B Drug Discount Program;

20 (4) the aggregate amount, by 340B entity type, paid to
21 contract pharmacies;

22 (5) the average markup imposed by each covered entity
23 on 340B-priced drugs organized by therapeutic class;

24 (6) the aggregate and transaction-level acquisition
25 cost paid by a 340B covered entity for all prescription
26 drugs organized by therapeutic class obtained under the

1 340B Drug Discount Program and dispensed or administered
2 to patients;

3 (7) the aggregate and transaction-level payment amount
4 received by a 340B covered entity for all drugs organized
5 by therapeutic class obtained under the 340B Drug Discount
6 Program and dispensed or administered to patients;

7 (8) with respect to 340B covered entities, a list of
8 contract pharmacies contracted with the 340B covered
9 entity to dispense 340B covered drugs;

10 (9) the aggregate and transaction-level payment made
11 to contract pharmacies to dispense drugs obtained under
12 the 340B Drug Discount Program;

13 (10) the following claims data:

14 (A) the number of claims for prescription drugs
15 described in paragraph (7) organized by therapeutic
16 class of drug; and

17 (B) the percentage of the 340B covered entity's
18 claims that included prescription drugs obtained under
19 the 340B Drug Discount Program;

20 (11) how the 340B covered entity uses any savings from
21 participating in the 340B Drug Discount Program, including
22 the amount of savings used for the provision of charity
23 care, community benefits (including identification of the
24 benefit program), and any similar program of providing
25 unreimbursed or subsidized health care;

26 (12) to the extent the information is available, the

1 percentage of total patients of the 340B covered entity
2 that were:

3 (A) served by a sliding fee scale for a
4 prescription drug dispensed or administered under the
5 340B Drug Discount Program;

6 (B) Medicaid customers and uninsured or
7 underinsured patients;

8 (C) racial and ethnic minority populations;

9 (D) patients residing in rural or Medically
10 Underserved Areas, including Governor's Exceptions,
11 designated by the Health Resources and Services
12 Administration, an agency of the United States
13 Department of Health and Human Services;

14 (E) populations with a higher prevalence of
15 chronic disease and poor health outcomes linked to
16 societal determinants of health; and

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

19 (13) with respect to covered entities, the 340B
20 covered entity's total operating costs;

21 (14) with respect to covered entities, the 340B
22 covered entity's total costs for community benefits,
23 including charity care;

24 (15) with respect to covered entities, a copy of the
25 340B covered entity's financial assistance policy for the
26 reporting year;

1 (16) identification of the parties involved in the
2 340B procurement and dispensing process for each covered
3 facility;

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

7 (18) the aggregate and transaction-level payment made
8 to a pharmacy benefit manager that provides pharmacy
9 benefit management services for a 340B covered entity
10 organized by therapeutic class of drug, if the information
11 has not already been submitted in a pharmaceutical
12 manufacturer 340B audit;

13 (19) the total cost and number of hours spent
14 preparing the data in response to the study;

15 (20) with respect to pharmaceutical manufacturers,
16 copies of any 340B audits conducted during the previous
17 calendar year;

18 (21) the specific pharmaceutical manufacturers that
19 are participating in the 340B Drug Discount Program in
20 Illinois;

21 (22) with respect to pharmaceutical manufacturers, any
22 restrictions placed by that manufacturer on participation
23 in the 340B Drug Discount Program, any accompanying data
24 supporting those restrictions, and the reasoning;

25 (23) a description of the impact of the 340B Drug
26 Discount Program on the patients and the community served

1 by each 340B covered entity; and

2 (24) with respect to pharmaceutical manufacturers, and
3 for the purpose of analyzing the impact of the 340B Drug
4 Discount Program, the aggregate amount of all 340B
5 discounts provided for each calendar year beginning in
6 2020.

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

9 (c) The Department of Insurance shall request the
10 information described in subsection (a). All 340B covered
11 entities, insurers as defined in subsection (a-5) of Section
12 513b1 of the Illinois Insurance Code, pharmacy benefit
13 managers, third-party administrators, pharmaceutical
14 manufacturers doing business in the State of Illinois, and
15 administrative service organizations of the State Employees
16 Group Insurance Program shall comply with requests for
17 information relevant to subsection (a) from the Department of
18 Insurance in the format prescribed and within the timeframe
19 specified. The Department of Insurance is hereby granted
20 specific authority to fine any 340B covered entity, insurer,
21 pharmacy benefit manager, third-party administrator, or
22 administrative services organization that fails to comply with
23 this Section within 30 calendar days after the due date
24 specified by the Department of Insurance, at a rate of \$100 per
25 day for each day beyond 30 calendar days for federally
26 qualified health centers and historical safety-net hospitals,

1 and at a rate of \$500 per day for each day beyond 30 calendar
2 days for all other entities, that the information is past due.
3 Fines collected pursuant to this subsection shall be deposited
4 into the Vulnerable Community Hospital Capital Investment
5 Fund, which is hereby created as a special fund in the State
6 treasury. All moneys in the Vulnerable Community Hospital
7 Capital Investment Fund shall be used to support the health
8 equity framework for supporting access to health care,
9 creating sustainability, and supporting the implementation of
10 the 340B Drug Discount Program. The Department of Insurance
11 shall enforce this Section pursuant to the powers granted to
12 it by law, including, but not limited to, the powers provided
13 under Article XXIV of the Illinois Insurance Code. Subsections
14 (2) through (5) of Section 403A of the Illinois Insurance Code
15 shall apply to the imposition of any fine.

16 (d) Subject to subsection (e), the Department of Insurance
17 shall maintain the confidentiality of any information
18 submitted under subsection (c) for which the submitting person
19 or entity includes a request that meets the criteria in
20 paragraph (g) of subsection (1) of Section 7 of the Freedom of
21 Information Act, and the information shall not be subject to
22 subpoena in any private civil litigation in this State.
23 Nothing in this Section shall prevent the Department of
24 Insurance from furnishing information collected from 340B
25 covered entities or pharmaceutical manufacturers to State or
26 federal authorities that may investigate, prosecute, or pursue

1 other legal action against a 340B covered entity or
2 pharmaceutical manufacturer for violations of 42 U.S.C. 256b
3 or any applicable State law.

4 (e) The Department of Insurance shall submit a report of
5 the findings of its study to the General Assembly and to the
6 Governor by July 1, 2028. The report shall provide findings
7 aggregated across 340B covered entities and pharmaceutical
8 manufacturers and shall not disclose information or data
9 attributed to any specific 340B covered entity or
10 pharmaceutical manufacturer. The report shall note any
11 requests for information from the Department of Insurance
12 where the requested information was never submitted. The
13 report shall address whether the data collected by the
14 Department indicates a need for annual or biennial reporting
15 by 340B covered entities. The report may include any
16 aggregated findings related to the populations identified in
17 paragraph (16) of subsection (a). The report shall address
18 whether the data collected by the Department indicates a need
19 for biennial reporting by 340B covered entities.

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

21 Section 900. If and only if House Bill 2371 of the 104th
22 General Assembly becomes law, then the Patient Access to
23 Pharmacy Protection Act is amended by changing Section 40 as
24 follows:

1 (10400HB2371sam002, Sec. 40)

2 Sec. 40. Enforcement.

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

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

12 (1) temporary, preliminary, or permanent injunctive
13 relief for any act, policy, or practice that violates this
14 Act;

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

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

19 (4) any other relief.

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

24 (Source: 10400HB2371sam002.)

1 Section 905. The State Finance Act is amended by adding
2 Section 5.1038 as follows:

3 (30 ILCS 105/5.1038 new)

4 Sec. 5.1038. The Vulnerable Community Hospital Capital
5 Investment Fund.

6 Section 999. Effective date. This Act takes effect upon
7 becoming law, but Section 900 does not take effect at all
8 unless House Bill 2371 of the 104th General Assembly, as
9 amended by Senate Amendment No. 2, becomes law.".