

1 AN ACT concerning auditing.

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 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
17 communities.

18 (2) Congress intended the 340B Drug Discount Program
19 to provide discounts to 340B covered entities that provide
20 direct health care to uninsured uninsured and underinsured
21 vulnerable patients.

22 (3) The appropriate and effective use of the 340B Drug
23 Discount Program is essential for improving health

1 outcomes, particularly for vulnerable and underserved
2 communities in rural, suburban, and urban areas throughout
3 Illinois meeting the definitions of vulnerable
4 communities.

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

15 (5) To protect vulnerable communities, the General
16 Assembly must pass the Health Equity Infrastructure Access
17 and Stabilization Act. This includes creation of and
18 funding of the following components:

19 (A) the Vulnerable Community Health Capital Fund
20 Voluntary investment program;

21 (B) the Community Health Networks of Continuum
22 Care;

23 (C) the Illinois Safety Net Hospital Package;

24 (D) the Behavioral and Mental Health (BMH) Access
25 and Expansion Fund;

26 (E) the Stabilization and Sustainability

1 Operational Funding Program;

2 (F) the 340B Grantee Contract Pharmacy Access Act
3 integration;

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

6 (H) the Unified Health Equity Omnibus Package.

7 (6) Savings associated with the federal 340B Drug
8 Discount Program may support the financial stability of
9 hospitals, FQHCs, Ryan White providers, rural providers,
10 and other historical safety-net institutions serving
11 vulnerable communities experiencing health care access
12 shortages, provider scarcity, or risk of service reduction
13 or closure.

14 (7) Vulnerable communities in the State of Illinois
15 are populations or geographic areas whose residents
16 experience disproportionate barriers to achieving optimal
17 health outcomes due to cumulative social, economic,
18 environmental, and structural disadvantages. These
19 communities are characterized by elevated health
20 disparities, limited access to health care services, and
21 increased exposure to risk factors, such as poverty,
22 inadequate insurance coverage, geographic isolation,
23 systemic discrimination, and unmet social determinants of
24 health, including housing, transportation, food security,
25 and environmental conditions, and who, as a result of
26 these conditions, experience reduced access to timely,

1 culturally competent, and geographically proximate
2 community-based hospital and health care services.

3 (8) This Act is intended solely to establish a
4 state-level reporting and transparency framework to allow
5 the 340B program to be evaluated, and shall not regulate
6 pricing, reimbursement, or participation in the federal
7 340B Program.

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

9 "340B covered entity" or "covered entity" means a covered
10 entity as defined in 42 U.S.C. 256b(a)(4), with a service
11 address in Illinois as of January 1 of the reporting year.

12 "340B Drug Discount Program" means the program established
13 under Section 340B of the federal Public Health Service Act,
14 42 U.S.C. 256b, and as stated in Section 10 of the Patient
15 Access to Pharmacy Protection Act.

16 "340B entity type" means the designation of the 340B
17 covered entity according to the entity types specified in 42
18 U.S.C. 256b(a)(4), and as stated in Section 10 of the Patient
19 Access to Pharmacy Protection Act.

20 "340B identification number" means the unique
21 identification number provided by the Health Resources and
22 Services Administration to identify a 340B-eligible entity in
23 the 340B Office of Pharmacy Affairs Information System.

24 "340B contract pharmacy" means a pharmacy that enters into
25 a contract with a 340B covered entity to provide services to

1 the 340B covered entity's patients, including dispensing
2 entity-owned 340B drugs, and as stated in Section 10 of the
3 Patient Access to Pharmacy Protection Act.

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

7 "Pharmaceutical manufacturer" means an entity that is
8 engaged in:

9 (1) the production, preparation, propagation,
10 compounding, conversion, or processing of prescription
11 drug products, either directly or indirectly by extraction
12 from substances of natural origin, independently by means
13 of chemical synthesis, or by a combination of extraction
14 and chemical synthesis; or

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

17 "Pharmaceutical manufacturer" does not include a wholesale
18 distributor of drugs or a retail pharmacy licensed under State
19 law.

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

21 (1) low-income and economically disadvantaged
22 populations, including households below 80% of area median
23 income;

24 (2) racial and ethnic minority populations and
25 historically marginalized groups experiencing systemic
26 inequities;

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

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

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

8 (6) individuals with disabilities, older adults,
9 LGBTQ+ populations, and justice-involved individuals
10 identified as equity-focused populations under Illinois
11 law.

12 Section 15. 340B Drug Discount Program study.

13 (a) As soon as practical after the effective date of this
14 Act, the Department of Insurance shall conduct a comprehensive
15 study of how 340B covered entities and pharmaceutical
16 manufacturers within Illinois participate in the 340B Drug
17 Discount Program. The study shall include an examination of
18 the impact of this participation by 340B covered entities on
19 State health programs, such as Medicaid and the State
20 Employees Group Insurance Program. The study shall include,
21 but not be limited to, an assessment of:

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

23 (A) name;

24 (B) service address;

25 (C) 340B identification number; and

1 (D) 340B designation, as specified in 42 U.S.C
2 256b(a)(4);

3 (2) with respect to covered entities, the aggregate
4 amount, by 340B entity type, of 340B revenue, defined as
5 the total patient and payer reimbursement less the total
6 340B acquisition cost, generated by 340B covered entities
7 from both self-administered and physician-administered
8 drugs;

9 (3) the aggregate amount, by 340B entity type, spent
10 on third-party administrators for the management of the
11 340B Drug Discount Program;

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

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

16 (6) the aggregate and transaction-level acquisition
17 cost paid by a 340B covered entity for all prescription
18 drugs organized by therapeutic class obtained under the
19 340B Drug Discount Program and dispensed or administered
20 to patients;

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

25 (8) with respect to 340B covered entities, a list of
26 contract pharmacies contracted with the 340B covered

1 entity to dispense 340B covered drugs;

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

5 (10) the following claims data:

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

9 (B) the percentage of the 340B covered entity's
10 claims that included prescription drugs obtained under
11 the 340B Drug Discount Program;

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

18 (12) to the extent the information is available, the
19 percentage of total patients of the 340B covered entity
20 that were:

21 (A) served by a sliding fee scale for a
22 prescription drug dispensed or administered under the
23 340B Drug Discount Program;

24 (B) Medicaid customers and uninsured or
25 underinsured patients;

26 (C) racial and ethnic minority populations;

1 (D) patients residing in rural or Medically
2 Underserved Areas, including Governor's Exceptions,
3 designated by the Health Resources and Services
4 Administration, an agency of the United States
5 Department of Health and Human Services;

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

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

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

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

16 (15) with respect to covered entities, a copy of the
17 340B covered entity's financial assistance policy for the
18 reporting year;

19 (16) identification of the parties involved in the
20 340B procurement and dispensing process for each covered
21 facility;

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

25 (18) the aggregate and transaction-level payment made
26 to a pharmacy benefit manager that provides pharmacy

1 benefit management services for a 340B covered entity
2 organized by therapeutic class of drug, if the information
3 has not already been submitted in a pharmaceutical
4 manufacturer 340B audit;

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

7 (20) with respect to pharmaceutical manufacturers,
8 copies of any 340B audits conducted during the previous
9 calendar year;

10 (21) the specific pharmaceutical manufacturers that
11 are participating in the 340B Drug Discount Program in
12 Illinois;

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

17 (23) a description of the impact of the 340B Drug
18 Discount Program on the patients and the community served
19 by each 340B covered entity; and

20 (24) with respect to pharmaceutical manufacturers, and
21 for the purpose of analyzing the impact of the 340B Drug
22 Discount Program, the aggregate amount of all 340B
23 discounts provided for each calendar year beginning in
24 2020.

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

1 (c) The Department of Insurance shall request the
2 information described in subsection (a). All 340B covered
3 entities, insurers as defined in subsection (a-5) of Section
4 513b1 of the Illinois Insurance Code, pharmacy benefit
5 managers, third-party administrators, pharmaceutical
6 manufacturers doing business in the State of Illinois, and
7 administrative service organizations of the State Employees
8 Group Insurance Program shall comply with requests for
9 information relevant to subsection (a) from the Department of
10 Insurance in the format prescribed and within the timeframe
11 specified. The Department of Insurance is hereby granted
12 specific authority to fine any 340B covered entity, insurer,
13 pharmacy benefit manager, third-party administrator, or
14 administrative services organization that fails to comply with
15 this Section within 30 calendar days after the due date
16 specified by the Department of Insurance, at a rate of \$100 per
17 day for each day beyond 30 calendar days for federally
18 qualified health centers and historical safety-net hospitals,
19 and at a rate of \$500 per day for each day beyond 30 calendar
20 days for all other entities, that the information is past due.
21 Fines collected pursuant to this subsection shall be deposited
22 into the Vulnerable Community Hospital Capital Investment
23 Fund, which is hereby created as a special fund in the State
24 treasury. All moneys in the Vulnerable Community Hospital
25 Capital Investment Fund shall be used to support the health
26 equity framework for supporting access to health care,

1 creating sustainability, and supporting the implementation of
2 the 340B Drug Discount Program. The Department of Insurance
3 shall enforce this Section pursuant to the powers granted to
4 it by law, including, but not limited to, the powers provided
5 under Article XXIV of the Illinois Insurance Code. Subsections
6 (2) through (5) of Section 403A of the Illinois Insurance Code
7 shall apply to the imposition of any fine.

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

22 (e) The Department of Insurance shall submit a report of
23 the findings of its study to the General Assembly and to the
24 Governor by July 1, 2028. The report shall provide findings
25 aggregated across 340B covered entities and pharmaceutical
26 manufacturers and shall not disclose information or data

1 attributed to any specific 340B covered entity or
2 pharmaceutical manufacturer. The report shall note any
3 requests for information from the Department of Insurance
4 where the requested information was never submitted. The
5 report shall address whether the data collected by the
6 Department indicates a need for annual or biennial reporting
7 by 340B covered entities. The report may include any
8 aggregated findings related to the populations identified in
9 paragraph (12) of subsection (a). The report shall address
10 whether the data collected by the Department indicates a need
11 for biennial reporting by 340B covered entities.

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

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

17 (10400HB2371sam002, Sec. 40)

18 Sec. 40. Enforcement.

19 (a) The Attorney General is authorized to enforce this Act
20 ~~under its general authority under the Attorney General Act. If~~
21 the Attorney General has reasonable cause to believe that
22 there is or has been a violation of Section 15 of this Act,
23 then the Attorney General may commence a civil action in the

1 name of the People of the State of Illinois to enforce the
2 provisions of this Act in the appropriate circuit court.

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

5 (1) temporary, preliminary, or permanent injunctive
6 relief for any act, policy, or practice that violates this
7 Act;

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

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

12 (4) any other relief.

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

17 (Source: 10400HB2371sam002.)

18 Section 905. The State Finance Act is amended by adding
19 Section 5.1038 as follows:

20 (30 ILCS 105/5.1038 new)

21 Sec. 5.1038. The Vulnerable Community Hospital Capital
22 Investment Fund.

23 Section 999. Effective date. This Act takes effect upon
24 becoming law, but Section 900 does not take effect at all

1 unless House Bill 2371 of the 104th General Assembly, as
2 amended by Senate Amendment No. 2, becomes law.