

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 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 an entity
10 in Illinois that qualifies as a covered entity under Section
11 340B of the federal Public Health Service Act, 42 U.S.C.
12 256b(a)(4).

13 "340B Drug Discount Program" means the program established
14 under Section 340B of the federal Public Health Service Act,
15 42 U.S.C. 256b.

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).

19 "340B identification number" means the unique
20 identification number provided by the Health Resources and
21 Services Administration to identify a 340B-eligible entity in
22 the 340B Office of Pharmacy Affairs Information System.

23 "340B contract pharmacy" means any pharmacy that is under
24 contract with a 340B covered entity to dispense 340B drugs on
25 behalf of the 340B covered entity and is either (i) located in

1 Illinois and qualifies as a pharmacy under Section 3 of the
2 Pharmacy Practice Act; or (ii) is located in a state,
3 commonwealth, or territory of the United States, other than
4 Illinois, and dispenses 340B drugs on behalf of the 340B
5 covered entity.

6 "340B grantee" means an entity in Illinois that qualifies
7 as a covered entity under subparagraphs (A)-(K) of paragraph
8 (4) of subsection (a) of Section 340B of the federal Public
9 Health Service Act, 42 U.S.C. 256b(a)(4)(A)-(K).

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

13 "Hospital" means a hospital licensed under the Hospital
14 Licensing Act or University of Illinois Hospital Act.

15 "Pharmaceutical manufacturer" has the meaning given to the
16 term "manufacturer" in the Wholesale Drug Distribution
17 Licensing Act.

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

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

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

24 (1) low-income and economically disadvantaged
25 populations, including households below 80% of area median
26 income;

1 (2) racial and ethnic minority populations and
2 historically marginalized groups experiencing systemic
3 inequities;

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

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

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

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

15 Section 15. 340B Drug Discount Program study.

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

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

- 1 (A) name;
- 2 (B) service address;
- 3 (C) 340B identification number; and
- 4 (D) 340B designation, as specified in 42 U.S.C
- 5 256b(a)(4);
- 6 (2) the aggregate amount, by 340B entity type, spent
- 7 on third-party administrators for the management of the
- 8 340B Drug Discount Program;
- 9 (3) the average difference between the cost imposed by
- 10 each covered entity on 340B-priced drugs and the
- 11 reimbursement rate for 340B drugs, organized by
- 12 therapeutic class;
- 13 (4) the aggregate and transaction-level acquisition
- 14 cost paid by a 340B covered entity for all prescription
- 15 drugs organized by therapeutic class obtained under the
- 16 340B Drug Discount Program and dispensed or administered
- 17 to patients;
- 18 (5) the aggregate and transaction-level payment amount
- 19 received by a 340B covered entity for all drugs organized
- 20 by therapeutic class obtained under the 340B Drug Discount
- 21 Program and dispensed or administered to patients;
- 22 (6) with respect to 340B covered entities, a list of
- 23 contract pharmacies contracted with the 340B covered
- 24 entity to dispense 340B covered drugs;
- 25 (7) the aggregate and transaction-level payment made
- 26 to contract pharmacies to dispense drugs obtained under

1 the 340B Drug Discount Program;

2 (8) how the 340B covered entity uses any savings from
3 participating in the 340B Drug Discount Program, including
4 the total amount of 340B savings used for the provision of
5 charity care, community benefits (including identification
6 of the benefit program), any similar program of providing
7 unreimbursed or subsidized health care, and any remaining
8 savings for other purposes;

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

12 (A) served by a sliding fee scale for a
13 prescription drug dispensed or administered under the
14 340B Drug Discount Program;

15 (B) Medicaid customers and uninsured or
16 underinsured patients;

17 (C) racial and ethnic minority populations;

18 (D) patients residing in rural or Medically
19 Underserved Areas, including Governor's Exceptions,
20 designated by the Health Resources and Services
21 Administration, an agency of the United States
22 Department of Health and Human Services;

23 (E) populations with a higher prevalence of
24 chronic disease and poor health outcomes linked to
25 societal determinants of health; and

26 (F) individuals with disabilities, older adults,

1 LGBTQ+ populations, and justice-involved individuals;

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

4 (11) with respect to covered entities, a copy of the
5 340B covered entity's financial assistance policy for the
6 reporting year;

7 (12) identification of the parties involved in the
8 340B procurement and dispensing process for each covered
9 facility;

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

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

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

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

23 (17) the specific pharmaceutical manufacturers that
24 are participating in the 340B Drug Discount Program in
25 Illinois;

26 (18) with respect to pharmaceutical manufacturers, any

1 restrictions placed by that manufacturer on participation
2 in the 340B Drug Discount Program, any accompanying data
3 supporting those restrictions, and the reasoning;

4 (19) a description of the impact of the 340B Drug
5 Discount Program on the patients and the community served
6 by each 340B covered entity;

7 (20) with respect to pharmaceutical manufacturers, and
8 for the purpose of analyzing the impact of the 340B Drug
9 Discount Program, the aggregate amount of all 340B
10 discounts provided for each calendar year beginning in
11 2020; and

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

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

18 (c) The Department of Insurance shall request the
19 information described in subsection (a) in a format designated
20 by the Department. All 340B covered entities, and
21 pharmaceutical manufacturers doing business in the State of
22 Illinois, shall comply with requests for information relevant
23 to subsection (a) from the Department of Insurance in the
24 format prescribed and within the timeframe specified. Failure
25 by a covered entity or pharmaceutical manufacturer to submit
26 all requested information described in subsection (a) within

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

20 (d) Subject to subsection (e), the Department of Insurance
21 shall maintain the confidentiality of any information
22 submitted under subsection (c) for which the submitting person
23 or entity includes a request that meets the criteria in
24 paragraph (g) of subsection (1) of Section 7 of the Freedom of
25 Information Act, and the information shall not be subject to
26 subpoena in any private civil litigation in this State.

1 Nothing in this Section shall prevent the Department of
2 Insurance from furnishing information collected from 340B
3 covered entities or pharmaceutical manufacturers to State or
4 federal authorities that may investigate, prosecute, or pursue
5 other legal action against a 340B covered entity or
6 pharmaceutical manufacturer for violations of 42 U.S.C. 256b
7 or any applicable State law.

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

24 Section 20. Severability. If any provision of this Act or
25 the Patient Access to Pharmacy Act is held invalid by a court,

1 the validity of the remainder of this Act and the Patient
2 Access to Pharmacy Act shall not be affected by that
3 determination of invalidity. If the applicability of any
4 provision of this Act or the Patient Access to Pharmacy Act to
5 any person or circumstance is held invalid by a court, the
6 applicability of that provision to other persons or
7 circumstances shall not be affected by that determination of
8 invalidity.

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

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

14 (10400HB2371sam002, Sec. 40)

15 Sec. 40. Enforcement.

16 (a) The Attorney General is authorized to enforce this Act
17 ~~under its general authority under the Attorney General Act. If~~
18 the Attorney General has reasonable cause to believe that
19 there is or has been a violation of Section 15 of this Act,
20 then the Attorney General may commence a civil action in the
21 name of the People of the State of Illinois to enforce the
22 provisions of this Act in the appropriate circuit court.

23 (b) Upon finding a violation of Section 15 of this Act, a

1 court may order:

2 (1) temporary, preliminary, or permanent injunctive
3 relief for any act, policy, or practice that violates this
4 Act;

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

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

9 (4) any other relief.

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

14 (Source: 10400HB2371sam002.)

15 (10400HB2371sam002, Sec. 99)

16 Sec. 99. Effective date. This Act takes effect upon
17 becoming law or on the effective date of House Bill 4327 of the
18 104th General Assembly, whichever is later; however, this Act
19 does not take effect at all unless House Bill 4327 of the 104th
20 General Assembly becomes law.

21 (Source: 10400HB2371sam002.)

22 Section 905. The State Finance Act is amended by adding
23 Section 5.1038 as follows:

1 (30 ILCS 105/5.1038 new)

2 Sec. 5.1038. The Vulnerable Community Hospital Capital
3 Investment Fund.

4 Section 999. Effective date. This Act takes effect upon
5 becoming law or on the effective date of House Bill 2371 of the
6 104th General Assembly, as amended by Senate Amendment No. 2,
7 whichever is later; however, this Act does not take effect at
8 all unless House Bill 2371 of the 104th General Assembly, as
9 amended by Senate Amendment No. 2, becomes law.