

1 AN ACT concerning regulation.

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
5 Patient Access to Pharmacy Protection Act.

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

7 (1) It is within the traditional authority of the State to
8 regulate the acquisition and delivery of drugs to pharmacies
9 and providers.

10 (2) The federal 340B statute is silent on distribution of
11 340B-acquired drugs to 340B covered entities and their
12 contract pharmacy partners.

13 (3) The State's compelling interest in preserving and
14 improving access to health care services requires it to ensure
15 that 340B covered entities continue to be allowed to contract
16 with pharmacies to receive 340B drugs and dispense them to the
17 patients of 340B covered entities in accordance with federal
18 law.

19 (4) Addressing accessibility of these life-saving
20 medications is a matter of health, safety, and welfare for the
21 people of the State of Illinois.

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

1 "340B contract pharmacy" means any pharmacy that is under
2 contract with a 340B covered entity to dispense 340B drugs on
3 behalf of the 340B covered entity and is either (i) located in
4 Illinois and qualifies as a pharmacy under Section 3 of the
5 Pharmacy Practice Act; or (ii) is located in a state,
6 commonwealth, or territory of the United States, other than
7 Illinois, and dispenses 340B drugs on behalf of the 340B
8 covered entity.

9 "340B covered entity" means an entity in Illinois that
10 qualifies as a covered entity under Section 340B of the
11 federal Public Health Service Act, 42 U.S.C. 256b(a)(4).

12 "340B drug" means a drug that has been subject to any offer
13 for reduced prices by a manufacturer pursuant to 42 U.S.C.
14 256b and is purchased by a 340B covered entity.

15 "340B drug discount program" means the program established
16 under Section 340B of the federal Public Health Service Act,
17 42 U.S.C. 256b.

18 "340B grantee" means an entity in Illinois that qualifies
19 as a covered entity under subparagraphs (A)-(K) of paragraph
20 (4) of subsection (a) of Section 340B of the federal Public
21 Health Service Act, 42 U.S.C. 256b(a)(4)(A)-(K).

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

25 "Hospital" means a hospital licensed under the Hospital
26 Licensing Act or University of Illinois Hospital Act.

1 "Manufacturer" or "Pharmaceutical Manufacturer" has the
2 meaning given to the term "manufacturer" in the Wholesale Drug
3 Distribution Licensing Act.

4 "Person" includes a natural person, partnership,
5 association, corporation, or any other legal business entity.
6 "Person" does not include any federal or State government
7 entity or body.

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

10 Section 15. Protection of patient access to pharmacy.

11 (a) No person, including a pharmaceutical manufacturer,
12 may deny, restrict, prohibit, condition, or otherwise
13 interfere with, either directly or indirectly, the acquisition
14 of a 340B drug by, or delivery of a 340B drug to, a 340B
15 covered entity or a 340B contract pharmacy authorized to
16 receive 340B drugs on behalf of the 340B covered entity unless
17 the receipt is prohibited by federal law.

18 (b) No person, including a pharmaceutical manufacturer,
19 may impose any restriction on the ability of a 340B covered
20 entity to contract with or designate a 340B contract pharmacy,
21 including restrictions relating to the number, location,
22 ownership, or type of 340B contract pharmacy.

23 (c) No person, including a pharmaceutical manufacturer,
24 may require or compel a 340B covered entity or 340B contract
25 pharmacy to:

1 (1) submit or otherwise provide ingredient cost or
2 pricing data pertinent to 340B drugs unless required by
3 State or federal law;

4 (2) institute requirements in any way relating to how
5 a 340B covered entity manages its inventory of 340B drugs
6 that are not required by a State or federal agency,
7 including requirements relating to the frequency or scope
8 of audits of inventory management systems of a 340B
9 covered entity or a 340B contract pharmacy; or

10 (3) submit data or information that is not required by
11 a State or federal law as a condition for a 340B covered
12 entity, its 340B contract pharmacy, or a location
13 otherwise authorized by a 340B covered entity to receive
14 340B drugs.

15 (d) Each individual transaction, as defined in 21 U.S.C.
16 360eee-24, of 340B drugs that is subject to a prohibited act in
17 subsections (a) and (b) shall constitute a separate violation
18 of this Act.

19 Section 20. Reporting. On or before August 1, 2026 and
20 each August 1 thereafter, a 340B covered entity shall submit a
21 report to the General Assembly pursuant to this Section. For
22 the purposes of this Section, the following covered entities
23 are exempt until January 1, 2029 and will report on or before
24 August 1, 2029 and each August 1 thereafter: hospitals with
25 fewer than 100 licensed beds, Critical Access Hospitals,

1 Safety-Net Hospitals, and 340B grantees. The report must
2 include all of the following for the 340B covered entity's
3 340B program:

4 (1) the name of the 340B covered entity submitting the
5 report;

6 (2) a copy of the 340B covered entity's annual 340B
7 program recertification;

8 (3) whether a community benefits plan report is
9 required under Section 20 of the Community Benefits Act
10 and, if so, a copy of the 340B covered entity's community
11 benefits plan report, including a description of the
12 amount of charity care provided by the 340B covered
13 entity;

14 (4) the aggregate acquisition cost for prescription
15 drugs obtained under the 340B program and dispensed or
16 administered to patients;

17 (5) the aggregate payment amount received for all
18 drugs obtained under the 340B program and dispensed or
19 administered to patients;

20 (6) the number of claims for prescription drugs
21 received under the 340B program;

22 (7) the percentage of the 340B covered entity's claims
23 that were for prescription drugs obtained under the 340B
24 program;

25 (8) a description of any adverse 340B program audits
26 within the preceding 12 months; and

1 (9) a description of the impact of the 340B program on
2 the patients and the community served by the 340B covered
3 entity.

4 Section 25. Medicaid study.

5 (a) By January 1, 2028, the Department of Healthcare and
6 Family Services shall report to the General Assembly on the
7 following for the total aggregated covered outpatient drug
8 units dispensed or administered in this State for the prior
9 calendar year in connection with the medical assistance
10 program under the Illinois Public Aid Code, categorized by (i)
11 fee-for-service and (ii) each managed care plan:

12 (1) the number of dispensed or administered covered
13 outpatient drug units;

14 (2) the number of dispensed or administered covered
15 outpatient drug units that were subject to a rebate under
16 42 U.S.C. 1396r-8; and

17 (3) a reasonable estimate of net costs or savings to
18 the State's medical assistance program due to 340B covered
19 entity purchases of covered outpatient drug units at 340B
20 pricing.

21 (b) To the extent the Department of Healthcare and Family
22 Services lacks information to provide a data element required
23 under subsection (a), it shall provide a reasonable estimate
24 based on all available information and an explanation of the
25 information that it lacks.

1 Section 30. 340B prescription drug applicability. Each
2 340B covered entity shall dispense or administer 340B drugs
3 only when in connection with an outpatient health care service
4 received by the patient within the last 18 months.

5 Section 35. Preventing duplication of 340B discounts. Each
6 340B covered entity shall develop and maintain a policy that
7 ensures it is not placing an order for a 340B drug to replenish
8 a prior pharmacy dispense if any other 340B covered entity
9 will place an order for a 340B drug to replenish the same prior
10 pharmacy dispense. The policy shall also include a process to
11 reimburse a manufacturer for any duplicate 340B discount the
12 covered entity receives. The policy shall be filed annually
13 with the General Assembly.

14 Section 40. Enforcement.

15 (a) The Attorney General is authorized to enforce this Act
16 under its general authority under the Attorney General Act.

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

19 (1) temporary, preliminary, or permanent injunctive
20 relief for any act, policy, or practice that violates this
21 Act;

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

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

3 (4) any other relief.

4 Section 45. Preemption.

5 (a) Nothing in this Act shall be construed or applied to be
6 less restrictive than federal law for a person regulated by
7 this Act.

8 (b) Nothing in this Act shall be construed or applied in a
9 manner that would conflict with:

10 (1) applicable federal law; or

11 (2) other laws of this State if the State law is
12 compatible with applicable federal law.

13 (c) Limited distribution of a drug required under 21
14 U.S.C. 355-1 may not to be construed as a violation of this
15 Act.

16 Section 97. Severability. If any provision of this Act or
17 its application to any person or circumstance is held invalid,
18 the invalidity of that provision or application does not
19 affect other provisions or applications of this Act that can
20 be given effect without the invalid provision or application.
21 Each paragraph defining "340B contract pharmacy" in Section 10
22 is severable.

23 Section 99. Effective date. This Act takes effect upon
24 becoming law.