



103RD GENERAL ASSEMBLY

State of Illinois

2023 and 2024

HB3256

Introduced 2/17/2023, by Rep. Nabeela Syed

SYNOPSIS AS INTRODUCED:

New Act
5 ILCS 140/7.5

Creates the Affordable Drug Manufacturing Act. Provides that the Department of Public Health shall enter into partnerships to increase competition, lower prices, and address shortages in the market for generic prescription drugs, to reduce the cost of prescription drugs for public and private purchasers, taxpayers, and consumers, and to increase patient access to affordable drugs. Requires the partnerships to result in the production or distribution of generic prescription drugs with the intent that these drugs be made widely available to public and private purchasers, providers and suppliers, and pharmacies. Provides that the Department shall comply with specified requirements when entering into partnerships or setting prices for generic prescription drugs. Requires the Department to submit separate reports to the General Assembly that (1) assess the feasibility of directly manufacturing generic prescription drugs and selling generic prescription drugs at a fair price; and (2) describe the status of all drugs targeted under the Act and analyze how the activities of the Department may impact competition, access to targeted drugs, the costs of those drugs, and the costs of generic prescription drugs to public and private purchasers. Contains other provisions. Amends the Freedom of Information Act to exempt certain information disclosed under the Affordable Drug Manufacturing Act from inspection and copying under the Act. Contains a severability provision. Effective July 1, 2023.

LRB103 27492 CPF 53866 b

1 AN ACT concerning health.

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 Affordable Drug Manufacturing Act.

6 Section 5. Definitions. In this Act:

7 "Department" means the Department of Public Health.

8 "Eligible prescription drug" means a prescription drug
9 that is not under patent or a biological product, as defined in
10 42 U.S.C. 262(i), that is not under patent.

11 "Generic prescription drug" means a drug that is approved
12 pursuant to an application referencing an eligible
13 prescription drug that is submitted under subsection (j) of
14 Section 505 of the Federal Food, Drug, and Cosmetic Act (21
15 U.S.C. 355(j)) or under subsection (k) of Section 351 of the
16 federal Public Health Service Act (42 U.S.C. 262(k)).

17 "Partnerships" include, but are not limited to, agreements
18 for the procurement of generic prescription drugs by way of
19 contracts or purchasing by a payor, State governmental agency,
20 group purchasing organization, nonprofit organization, or
21 other entity.

22 "Provider" means a hospital licensed under the Hospital
23 Licensing Act or organized under the University of Illinois

1 Hospital Act, a skilled nursing facility as that term is
2 defined under Section 2 of the Comprehensive Health Insurance
3 Plan Act, a comprehensive outpatient rehabilitation facility,
4 a home health agency as that term is defined under Section 2.04
5 of the Home Health, Home Services, and Home Nursing Agency
6 Licensing Act, a hospice as that term is defined under Section
7 2 of the Comprehensive Health Insurance Plan Act, a public
8 health clinic as that term is defined under Section 6-101 of
9 the Local Governmental and Governmental Employees Tort
10 Immunity Act, or a rehabilitation agency.

11 "Supplier" means a physician, surgeon, or other health
12 care practitioner or an entity other than a provider that
13 furnishes health care services.

14 Section 10. Cost of prescription drugs; partnerships.

15 (a) The Department shall enter into partnerships
16 consistent with subsection (b) of Section 15, in consultation
17 with other State agencies as necessary, to increase
18 competition, lower prices, and address shortages in the market
19 for generic prescription drugs, reduce the cost of generic
20 prescription drugs for public and private purchasers,
21 taxpayers, and consumers, and increase patient access to
22 affordable generic prescription drugs.

23 (b) Subject appropriation by the General Assembly for this
24 purpose, the Department may hire staff to oversee and
25 project-manage the partnerships for manufacturing or

1 distribution of generic prescription drugs.

2 Section 15. Generic prescription drug prices.

3 (a) The Department shall enter into partnerships resulting
4 in the production or distribution of generic prescription
5 drugs with the intent that these generic prescription drugs be
6 made widely available to public and private purchasers,
7 providers and suppliers, and pharmacies licensed under the
8 Pharmacy Practice Act, as appropriate. The generic
9 prescription drugs shall be produced or distributed by a drug
10 company or generic prescription drug manufacturer that is
11 registered with the United States Food and Drug
12 Administration.

13 (b) The Department shall comply with the following
14 requirements when entering into partnerships or setting prices
15 for generic prescription drugs:

16 (1) The Department shall only enter into partnerships
17 under subsection (a) to produce a generic prescription
18 drug at a price that results in savings, target failures
19 in the market for generic prescription drugs, and improve
20 patient access to affordable medications.

21 (2) For generic prescription drugs prioritized in
22 accordance with the criteria listed in paragraph (5), the
23 Department shall determine if viable pathways exist for
24 partnerships to manufacture or distribute generic
25 prescription drugs by examining the relevant legal,

1 market, policy, and regulatory factors.

2 (3) The Department shall consider the following, if
3 applicable, when setting the price of a generic
4 prescription drug under this Section:

5 (A) United States Food and Drug Administration
6 user fees.

7 (B) Abbreviated new drug application acquisition
8 costs, amortized over a 5-year period.

9 (C) Mandatory rebates.

10 (D) Total contracting and production costs for the
11 generic prescription drug, including a reasonable
12 amount for administrative, operating, and
13 rate-of-return expenses of the drug company or generic
14 prescription drug manufacturer.

15 (E) Research and development costs attributed to
16 the generic prescription drug over a 5-year period.

17 (F) Other initial start-up costs, amortized over a
18 5-year period.

19 (4) Each generic prescription drug shall be made
20 available to providers, patients, and purchasers at a
21 transparent price and without rebates, other than
22 federally required rebates.

23 (5) The Department shall prioritize the selection of
24 generic prescription drugs that have the greatest impact
25 on lowering drug costs to patients, increasing competition
26 and addressing shortages in the prescription drug market,

1 improving public health, or reducing the cost of
2 prescription drugs to public and private purchasers.

3 (c) In identifying generic prescription drugs to be
4 produced, the Department shall consider pharmacy spending data
5 from Medicaid and other entities for which the State pays the
6 cost of generic prescription drugs.

7 The partnerships entered into under subsection (a) shall
8 include the production of at least one form of insulin,
9 provided that a viable pathway for manufacturing a more
10 affordable form of insulin exists.

11 The Department shall prioritize generic prescription drugs
12 for chronic and high-cost conditions and shall consider
13 prioritizing those that can be delivered through mail order.

14 (d) The Department shall consult with all of the following
15 public and private purchasers to assist in developing a list
16 of generic prescription drugs to be manufactured or
17 distributed through partnerships and to determine the volume
18 of each generic prescription drug that can be procured over a
19 multiyear period to support a market for a lower-cost generic
20 prescription drug:

21 (1) Any public agency that is a purchaser.

22 (2) Health insurers holding a valid outstanding
23 certificate of authority from the Director of Insurance.

24 (3) Hospitals.

25 (4) Pharmacy benefit managers.

26 (e) Before entering into a partnership under subsection

1 (a), the Department shall determine minimum thresholds for
2 procurement of an entity's expected volume of a targeted
3 generic prescription drug from the company or manufacturer
4 over a multiyear period.

5 (f) The entities listed in paragraphs (2) through (5) of
6 subsection (d) shall not be required to purchase prescription
7 drugs from the Department or from entities that contract or
8 partner with the Department under this Act.

9 (g) The Department is not required to consult with every
10 entity listed in paragraphs (2) through (5) of subsection (d)
11 so long as purchaser engagement includes a reasonable
12 representation from those groups.

13 Section 20. Feasibility report.

14 (a) On or before July 1, 2025, the Department shall submit
15 a report to the General Assembly that assesses the feasibility
16 of the Department directly manufacturing generic prescription
17 drugs and selling generic prescription drugs at a fair price.
18 The report shall include an analysis of governance structure
19 options for manufacturing functions, including chartering a
20 private organization, public-private partnership, or public
21 board of directors.

22 (b) This Section is repealed on January 1, 2027.

23 Section 25. Status and analysis report.

24 (a) On or before July 1, 2024, the Department shall submit

1 a report to the General Assembly with:

2 (1) a description of the status of all drugs targeted
3 under this Act; and

4 (2) an analysis of how the activities of the
5 Department may impact competition, access to targeted
6 drugs, the costs of those drugs, and the costs of generic
7 prescription drugs for public and private purchasers.

8 (b) This Section is repealed on January 1, 2028.

9 Section 30. Nonpublic information; disclosure.
10 Notwithstanding any other provision of law, all nonpublic
11 information and documents obtained under this Act shall not be
12 required to be disclosed pursuant to the Freedom of
13 Information Act.

14 Section 35. The Freedom of Information Act is amended by
15 changing Section 7.5 as follows:

16 (5 ILCS 140/7.5)

17 Sec. 7.5. Statutory exemptions. To the extent provided for
18 by the statutes referenced below, the following shall be
19 exempt from inspection and copying:

20 (a) All information determined to be confidential
21 under Section 4002 of the Technology Advancement and
22 Development Act.

23 (b) Library circulation and order records identifying

1 library users with specific materials under the Library
2 Records Confidentiality Act.

3 (c) Applications, related documents, and medical
4 records received by the Experimental Organ Transplantation
5 Procedures Board and any and all documents or other
6 records prepared by the Experimental Organ Transplantation
7 Procedures Board or its staff relating to applications it
8 has received.

9 (d) Information and records held by the Department of
10 Public Health and its authorized representatives relating
11 to known or suspected cases of sexually transmissible
12 disease or any information the disclosure of which is
13 restricted under the Illinois Sexually Transmissible
14 Disease Control Act.

15 (e) Information the disclosure of which is exempted
16 under Section 30 of the Radon Industry Licensing Act.

17 (f) Firm performance evaluations under Section 55 of
18 the Architectural, Engineering, and Land Surveying
19 Qualifications Based Selection Act.

20 (g) Information the disclosure of which is restricted
21 and exempted under Section 50 of the Illinois Prepaid
22 Tuition Act.

23 (h) Information the disclosure of which is exempted
24 under the State Officials and Employees Ethics Act, and
25 records of any lawfully created State or local inspector
26 general's office that would be exempt if created or

1 obtained by an Executive Inspector General's office under
2 that Act.

3 (i) Information contained in a local emergency energy
4 plan submitted to a municipality in accordance with a
5 local emergency energy plan ordinance that is adopted
6 under Section 11-21.5-5 of the Illinois Municipal Code.

7 (j) Information and data concerning the distribution
8 of surcharge moneys collected and remitted by carriers
9 under the Emergency Telephone System Act.

10 (k) Law enforcement officer identification information
11 or driver identification information compiled by a law
12 enforcement agency or the Department of Transportation
13 under Section 11-212 of the Illinois Vehicle Code.

14 (l) Records and information provided to a residential
15 health care facility resident sexual assault and death
16 review team or the Executive Council under the Abuse
17 Prevention Review Team Act.

18 (m) Information provided to the predatory lending
19 database created pursuant to Article 3 of the Residential
20 Real Property Disclosure Act, except to the extent
21 authorized under that Article.

22 (n) Defense budgets and petitions for certification of
23 compensation and expenses for court appointed trial
24 counsel as provided under Sections 10 and 15 of the
25 Capital Crimes Litigation Act. This subsection (n) shall
26 apply until the conclusion of the trial of the case, even

1 if the prosecution chooses not to pursue the death penalty
2 prior to trial or sentencing.

3 (o) Information that is prohibited from being
4 disclosed under Section 4 of the Illinois Health and
5 Hazardous Substances Registry Act.

6 (p) Security portions of system safety program plans,
7 investigation reports, surveys, schedules, lists, data, or
8 information compiled, collected, or prepared by or for the
9 Department of Transportation under Sections 2705-300 and
10 2705-616 of the Department of Transportation Law of the
11 Civil Administrative Code of Illinois, the Regional
12 Transportation Authority under Section 2.11 of the
13 Regional Transportation Authority Act, or the St. Clair
14 County Transit District under the Bi-State Transit Safety
15 Act.

16 (q) Information prohibited from being disclosed by the
17 Personnel Record Review Act.

18 (r) Information prohibited from being disclosed by the
19 Illinois School Student Records Act.

20 (s) Information the disclosure of which is restricted
21 under Section 5-108 of the Public Utilities Act.

22 (t) All identified or deidentified health information
23 in the form of health data or medical records contained
24 in, stored in, submitted to, transferred by, or released
25 from the Illinois Health Information Exchange, and
26 identified or deidentified health information in the form

1 of health data and medical records of the Illinois Health
2 Information Exchange in the possession of the Illinois
3 Health Information Exchange Office due to its
4 administration of the Illinois Health Information
5 Exchange. The terms "identified" and "deidentified" shall
6 be given the same meaning as in the Health Insurance
7 Portability and Accountability Act of 1996, Public Law
8 104-191, or any subsequent amendments thereto, and any
9 regulations promulgated thereunder.

10 (u) Records and information provided to an independent
11 team of experts under the Developmental Disability and
12 Mental Health Safety Act (also known as Brian's Law).

13 (v) Names and information of people who have applied
14 for or received Firearm Owner's Identification Cards under
15 the Firearm Owners Identification Card Act or applied for
16 or received a concealed carry license under the Firearm
17 Concealed Carry Act, unless otherwise authorized by the
18 Firearm Concealed Carry Act; and databases under the
19 Firearm Concealed Carry Act, records of the Concealed
20 Carry Licensing Review Board under the Firearm Concealed
21 Carry Act, and law enforcement agency objections under the
22 Firearm Concealed Carry Act.

23 (v-5) Records of the Firearm Owner's Identification
24 Card Review Board that are exempted from disclosure under
25 Section 10 of the Firearm Owners Identification Card Act.

26 (w) Personally identifiable information which is

1 exempted from disclosure under subsection (g) of Section
2 19.1 of the Toll Highway Act.

3 (x) Information which is exempted from disclosure
4 under Section 5-1014.3 of the Counties Code or Section
5 8-11-21 of the Illinois Municipal Code.

6 (y) Confidential information under the Adult
7 Protective Services Act and its predecessor enabling
8 statute, the Elder Abuse and Neglect Act, including
9 information about the identity and administrative finding
10 against any caregiver of a verified and substantiated
11 decision of abuse, neglect, or financial exploitation of
12 an eligible adult maintained in the Registry established
13 under Section 7.5 of the Adult Protective Services Act.

14 (z) Records and information provided to a fatality
15 review team or the Illinois Fatality Review Team Advisory
16 Council under Section 15 of the Adult Protective Services
17 Act.

18 (aa) Information which is exempted from disclosure
19 under Section 2.37 of the Wildlife Code.

20 (bb) Information which is or was prohibited from
21 disclosure by the Juvenile Court Act of 1987.

22 (cc) Recordings made under the Law Enforcement
23 Officer-Worn Body Camera Act, except to the extent
24 authorized under that Act.

25 (dd) Information that is prohibited from being
26 disclosed under Section 45 of the Condominium and Common

1 Interest Community Ombudsperson Act.

2 (ee) Information that is exempted from disclosure
3 under Section 30.1 of the Pharmacy Practice Act.

4 (ff) Information that is exempted from disclosure
5 under the Revised Uniform Unclaimed Property Act.

6 (gg) Information that is prohibited from being
7 disclosed under Section 7-603.5 of the Illinois Vehicle
8 Code.

9 (hh) Records that are exempt from disclosure under
10 Section 1A-16.7 of the Election Code.

11 (ii) Information which is exempted from disclosure
12 under Section 2505-800 of the Department of Revenue Law of
13 the Civil Administrative Code of Illinois.

14 (jj) Information and reports that are required to be
15 submitted to the Department of Labor by registering day
16 and temporary labor service agencies but are exempt from
17 disclosure under subsection (a-1) of Section 45 of the Day
18 and Temporary Labor Services Act.

19 (kk) Information prohibited from disclosure under the
20 Seizure and Forfeiture Reporting Act.

21 (ll) Information the disclosure of which is restricted
22 and exempted under Section 5-30.8 of the Illinois Public
23 Aid Code.

24 (mm) Records that are exempt from disclosure under
25 Section 4.2 of the Crime Victims Compensation Act.

26 (nn) Information that is exempt from disclosure under

1 Section 70 of the Higher Education Student Assistance Act.

2 (oo) Communications, notes, records, and reports
3 arising out of a peer support counseling session
4 prohibited from disclosure under the First Responders
5 Suicide Prevention Act.

6 (pp) Names and all identifying information relating to
7 an employee of an emergency services provider or law
8 enforcement agency under the First Responders Suicide
9 Prevention Act.

10 (qq) Information and records held by the Department of
11 Public Health and its authorized representatives collected
12 under the Reproductive Health Act.

13 (rr) Information that is exempt from disclosure under
14 the Cannabis Regulation and Tax Act.

15 (ss) Data reported by an employer to the Department of
16 Human Rights pursuant to Section 2-108 of the Illinois
17 Human Rights Act.

18 (tt) Recordings made under the Children's Advocacy
19 Center Act, except to the extent authorized under that
20 Act.

21 (uu) Information that is exempt from disclosure under
22 Section 50 of the Sexual Assault Evidence Submission Act.

23 (vv) Information that is exempt from disclosure under
24 subsections (f) and (j) of Section 5-36 of the Illinois
25 Public Aid Code.

26 (ww) Information that is exempt from disclosure under

1 Section 16.8 of the State Treasurer Act.

2 (xx) Information that is exempt from disclosure or
3 information that shall not be made public under the
4 Illinois Insurance Code.

5 (yy) Information prohibited from being disclosed under
6 the Illinois Educational Labor Relations Act.

7 (zz) Information prohibited from being disclosed under
8 the Illinois Public Labor Relations Act.

9 (aaa) Information prohibited from being disclosed
10 under Section 1-167 of the Illinois Pension Code.

11 (bbb) Information that is prohibited from disclosure
12 by the Illinois Police Training Act and the Illinois State
13 Police Act.

14 (ccc) Records exempt from disclosure under Section
15 2605-304 of the Illinois State Police Law of the Civil
16 Administrative Code of Illinois.

17 (ddd) Information prohibited from being disclosed
18 under Section 35 of the Address Confidentiality for
19 Victims of Domestic Violence, Sexual Assault, Human
20 Trafficking, or Stalking Act.

21 (eee) Information prohibited from being disclosed
22 under subsection (b) of Section 75 of the Domestic
23 Violence Fatality Review Act.

24 (fff) Images from cameras under the Expressway Camera
25 Act. This subsection (fff) is inoperative on and after
26 July 1, 2023.

1 (ggg) Information prohibited from disclosure under
2 paragraph (3) of subsection (a) of Section 14 of the Nurse
3 Agency Licensing Act.

4 (hhh) Information submitted to the Department of State
5 Police in an affidavit or application for an assault
6 weapon endorsement, assault weapon attachment endorsement,
7 .50 caliber rifle endorsement, or .50 caliber cartridge
8 endorsement under the Firearm Owners Identification Card
9 Act.

10 (iii) Information prohibited from being disclosed
11 under Section 30 of the Affordable Drug Manufacturing Act.

12 (Source: P.A. 101-13, eff. 6-12-19; 101-27, eff. 6-25-19;
13 101-81, eff. 7-12-19; 101-221, eff. 1-1-20; 101-236, eff.
14 1-1-20; 101-375, eff. 8-16-19; 101-377, eff. 8-16-19; 101-452,
15 eff. 1-1-20; 101-466, eff. 1-1-20; 101-600, eff. 12-6-19;
16 101-620, eff. 12-20-19; 101-649, eff. 7-7-20; 101-652, eff.
17 1-1-22; 101-656, eff. 3-23-21; 102-36, eff. 6-25-21; 102-237,
18 eff. 1-1-22; 102-292, eff. 1-1-22; 102-520, eff. 8-20-21;
19 102-559, eff. 8-20-21; 102-813, eff. 5-13-22; 102-946, eff.
20 7-1-22; 102-1042, eff. 6-3-22; 102-1116, eff. 1-10-23.)

21 Section 97. Severability. The provisions of this Act are
22 severable under Section 1.31 of the Statute on Statutes.

23 Section 99. Effective date. This Act takes effect July 1,
24 2023.