HB3583

LRB10214724CPF20077b

102ND GENERAL ASSEMBLY

State of Illinois

2021 and 2022

HB3583

Introduced 2/22/2021, by Rep. Dagmara Avelar

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 is exempt from disclosure under the Act. Contains a severability provision. Effective July 1, 2021.

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FISCAL NOTE ACT
MAY APPLY

A BILL FOR

AN ACT concerning health.

Be it enacted by the People of the State of Illinois, represented in the General Assembly:

Section 1. Short title. This Act may be cited as the Affordable Drug Manufacturing Act.

Section 5. Definitions. In this Act:

"Department" means the Department of Public Health.

"Generic drug" means a drug that is approved pursuant to subsection (j) of Section 355 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.) or a biosimilar, as defined under the federal Public Health Service Act (42 U.S.C. Sec. 262).

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

"Provider" means a hospital licensed under the Hospital Licensing Act or organized under the University of Illinois Hospital Act, a skilled nursing facility as that term is defined under Section 2 of the Comprehensive Health Insurance Plan Act, a comprehensive outpatient rehabilitation facility, a home health agency as that term is defined under Section 2.04

of the Home Health, Home Services, and Home Nursing Agency Licensing Act, a hospice as that term is defined under Section 2 of the Comprehensive Health Insurance Plan Act, a public health clinic as that term is defined under Section 6-101 of the Local Governmental and Governmental Employees Tort Immunity Act, or a rehabilitation agency.

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

Section 10. Cost of prescription drugs; partnerships.

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

(b) The Department may hire staff to oversee and project-manage the partnerships for manufacturing or distribution of generic prescription drugs, contingent upon an appropriation by the General Assembly for this purpose.

Section 15. Prescription drug prices.

(a) The Department shall enter into partnerships resulting

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 licensed under the Pharmacy Practice Act, as appropriate. The generic prescription drugs shall be produced or distributed by a drug company or generic drug manufacturer that is registered with the United States Food and Drug Administration.

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

(1) The Department shall only enter into partnerships pursuant to subsection (a) to produce a generic prescription drug at a price that results in savings, targets failures in the market for generic drugs, and improves patient access to affordable medications.

(2) For top drugs identified pursuant to the criteria listed in paragraph (5), the Department shall determine if viable pathways exist for partnerships to manufacture or distribute generic prescription drugs by examining the relevant legal, market, policy, and regulatory factors.

(3) The Department shall consider the following, if applicable, when setting the price of the generic prescription drug:

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

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

(C) Mandatory rebates.

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

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

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

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

(5) The Department shall prioritize the selection of generic prescription drugs that have the greatest impact on lowering drug costs to patients, increasing competition and addressing shortages in the prescription drug market, improving public health, or reducing the cost of prescription drugs to public and private purchasers.

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

The partnerships entered into pursuant to subsection (a) shall include the production of at least one form of insulin,

provided that a viable pathway for manufacturing a more affordable form of insulin exists.

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

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

(1) Any public agency that is a purchaser.

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

(3) Hospitals.

(4) Pharmacy benefit managers.

(e) Before entering into a partnership pursuant to this Section, the Department shall determine minimum thresholds for procurement of an entity's expected volume of a targeted drug from the company or manufacturer over a multiyear period.

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

(g) The Department shall not be required to consult with

every entity listed in paragraphs (2) through (5) of subsection (d), so long as purchaser engagement includes a reasonable representation from these groups.

Section 20. Feasibility report.

(a) On or before July 1, 2023, the Department shall submit a report to the General Assembly that assesses the feasibility of directly manufacturing generic prescription drugs and selling generic prescription drugs at a fair price. The report shall include an analysis of governance structure options for manufacturing functions, including chartering a private organization, public-private partnership, or public board of directors.

(b) This Section is repealed on January 1, 2025.

Section 25. Status and analysis report.

(a) On or before July 1, 2022, the Department shall report to the General Assembly on both of the following:

(1) A description of the status of all drugs targeted under this Act.

(2) An analysis of 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.

(b) This Section is repealed on January 1, 2026.

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

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

(5 ILCS 140/7.5)

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

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

(b) Library circulation and order records identifying library users with specific materials under the Library Records Confidentiality Act.

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

(d) Information and records held by the Department of

Public Health and its authorized representatives relating to known or suspected cases of sexually transmissible disease or any information the disclosure of which is restricted under the Illinois Sexually Transmissible Disease Control Act.

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

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

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

(h) Information the disclosure of which is exempted under the State Officials and Employees Ethics Act, and records of any lawfully created State or local inspector general's office that would be exempt if created or obtained by an Executive Inspector General's office under that Act.

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

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

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

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

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

(n) Defense budgets and petitions for certification of compensation and expenses for court appointed trial counsel as provided under Sections 10 and 15 of the Capital Crimes Litigation Act. This subsection (n) shall apply until the conclusion of the trial of the case, even if the prosecution chooses not to pursue the death penalty prior to trial or sentencing.

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

(p) Security portions of system safety program plans, investigation reports, surveys, schedules, lists, data, or information compiled, collected, or prepared by or for the Regional Transportation Authority under Section 2.11 of

the Regional Transportation Authority Act or the St. Clair County Transit District under the Bi-State Transit Safety Act.

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

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

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

(t) All identified or deidentified health information in the form of health data or medical records contained in, stored in, submitted to, transferred by, or released from the Illinois Health Information Exchange, and identified or deidentified health information in the form of health data and medical records of the Illinois Health Information Exchange in the possession of the Illinois Health Information Exchange Office due to its administration of the Illinois Health Information Exchange. The terms "identified" and "deidentified" shall be given the same meaning as in the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, or any subsequent amendments thereto, and any regulations promulgated thereunder.

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

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

(w) Personally identifiable information which is exempted from disclosure under subsection (g) of Section 19.1 of the Toll Highway Act.

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

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

(z) Records and information provided to a fatality review team or the Illinois Fatality Review Team Advisory

Council under Section 15 of the Adult Protective Services Act.

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

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

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

(dd) Information that is prohibited from being disclosed under Section 45 of the Condominium and Common Interest Community Ombudsperson Act.

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

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

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

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

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

(jj) Information and reports that are required to be submitted to the Department of Labor by registering day

and temporary labor service agencies but are exempt from disclosure under subsection (a-1) of Section 45 of the Day and Temporary Labor Services Act.

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

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

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

(nn) Information that is exempt from disclosure under Section 70 of the Higher Education Student Assistance Act.

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

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

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

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

(ss) Data reported by an employer to the Department of

Human Rights pursuant to Section 2-108 of the Illinois Human Rights Act.

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

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

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

(ww) Information that is exempt from disclosure under Section 16.8 of the State Treasurer Act.

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

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

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

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

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

(Source: P.A. 100-20, eff. 7-1-17; 100-22, eff. 1-1-18; 100-201, eff. 8-18-17; 100-373, eff. 1-1-18; 100-464, eff. 8-28-17; 100-465, eff. 8-31-17; 100-512, eff. 7-1-18; 100-517,

eff. 6-1-18; 100-646, eff. 7-27-18; 100-690, eff. 1-1-19; 100-863, eff. 8-14-18; 100-887, eff. 8-14-18; 101-13, eff. 6-12-19; 101-27, eff. 6-25-19; 101-81, eff. 7-12-19; 101-221, eff. 1-1-20; 101-236, eff. 1-1-20; 101-375, eff. 8-16-19; 101-377, eff. 8-16-19; 101-452, eff. 1-1-20; 101-466, eff. 1-1-20; 101-600, eff. 12-6-19; 101-620, eff 12-20-19; 101-649, eff. 7-7-20.)

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

Section 99. Effective date. This Act takes effect July 1, 2021.