HB4954

LRB104 17048 BAB 30463 b

104TH GENERAL ASSEMBLY

State of Illinois

2025 and 2026

HB4954

by Rep. Martha Deuter

SYNOPSIS AS INTRODUCED:

New Act

Creates the 340B Drug Pricing Program Reporting Act. On or before April 1, 2027 and each April 1 thereafter, requires a 340B covered entity to report the specified information and transactions to the Department of Public Health concerning the 340B covered entity's participation in or participation on behalf of the 340B covered entity in the federal 340B Program for the previous calendar year. On or before November 15, 2027 and each November 15 thereafter, requires the Department to prepare a report that aggregates the data submitted; submit the report to the General Assembly in an electronic format; and post the report on the Department's website. Provides that pharmaceutical manufacturers may request a 340B covered entity to provide specified information concerning the dispensation of 340B drugs. Sets forth provisions concerning penalties, exemptions for pharmaceutical manufacturers, and rulemaking. Provides that the Act is repealed on January 1, 2031. Effective immediately.

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A BILL FOR

AN ACT concerning regulation.

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 340B Drug Pricing Program Reporting Act.

Section 5. Definitions. In this Act:

"340B covered entity" or "covered entity" means a covered entity, as defined in 42 U.S.C. 256b(a)(4), with a service address in Illinois as of January 1 of the reporting year. "340B covered entity" includes all entity types and grantees and all facilities that are identified as child sites or grantee associated sites under the federal 340B Drug Pricing Program.

"340B Drug Pricing Program" or "340B Program" means the drug discount program established under 42 U.S.C. 256b.

"340B entity type" means the designation of the 340B covered entity according to the entity types specified in 42 U.S.C. 256b(a)(4).

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

"Contract pharmacy" means a pharmacy with which a 340B

covered entity has an arrangement to dispense drugs purchased under the 340B Drug Pricing Program.

"Department" means the Department of Public Health.

"Pharmaceutical manufacturer" means any entity that is engaged in:

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

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

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

Section 10. Registration and reporting requirements.

(a) On or before April 1, 2027 and each April 1 thereafter, a 340B covered entity shall report the following information and transactions to the Department concerning the 340B covered entity's participation in or participation on behalf of the 340B covered entity in the federal 340B Program for the previous calendar year:

(1) With respect to the 340B covered entity, the:

(A) name;

(B) service address;

(C) 340B Program identification number; and

(D) designation of entity type, as specified in 42 U.S.C. 256b(a)(4).

(2) The aggregate acquisition cost for all prescription drugs obtained under the 340B Program and dispensed or administered to patients.

(3) The aggregate payment amount received for all drugs obtained under the 340B Program and dispensed or administered to patients.

(4) The aggregate payment made to contract pharmacies to dispense drugs obtained under the 340B Program.

(5) The number of claims for prescription drugs described in paragraph (3).

(6) How the 340B covered entity uses any savings from participating in the 340B Program, including the amount of savings used for the provision of charity care, community benefits, or a similar program of providing unreimbursed or subsidized health care.

(7) The aggregate payments made to any other entity that is not a 340B covered entity and is not a contract pharmacy as described in paragraph (4) for managing any aspect of the 340B covered entity's 340B Program.

(8) The aggregate payment made for any other administering expense for the 340B Program.

(9) The aggregate number of prescription drugs

dispensed or administered to patients for which a payment was reported under paragraph (3).

(10) The percentage of the 340B covered entity's claims that were for prescription drugs obtained under the 340B Program.

(11) The number and percentage of low-income patients of the 340B covered entity that were served by a sliding fee scale for a prescription drug dispensed or administered under the 340B Program.

(12) The 340B covered entity's total operating costs.

(13) The 340B covered entity's total costs for charity care.

(14) A copy of the 340B covered entity's financial assistance policy for the reporting year.

(b) The information required to be reported under paragraphs (3) through (5) of subsection (a) must, to the extent feasible, be reported by payer type, including the following:

(1) Commercial.

(2) Medicaid.

(3) Medicare.

(4) Uninsured.

(c) The data submitted in the reports required under subsection (a) is confidential and is not available for public inspection.

(d) On or before November 15, 2027 and each November 15

thereafter, the Department shall:

(1) prepare a report that aggregates the data submitted under subsection (a);

(2) submit the report to the General Assembly in an electronic format; and

(3) post the report on the Department's website.

Section 15. Penalties. A 340B covered entity that fails to provide the information required under Section 10 by the date required shall pay to the Department a fine of $1,000 per day for which the information is past due.

Section 20. Exemptions for pharmaceutical manufacturers.

(a) Nothing in this Act shall deny, restrict, or prohibit a pharmaceutical manufacturer from obtaining the same data compiled and submitted by a 340B covered entity and provided to:

(1) payors for reimbursement; or

(2) any other entity managing any aspect of the 340B covered entity's 340B Program, such as third-party administrators.

(b) Pharmaceutical manufacturers may use the compiled data for purposes of identifying and investigating duplicate discounts or diversion and verifying that a request made by a 340B covered entity, its 340B contract pharmacy, or a location otherwise authorized by a 340B covered entity to receive 340B

drugs, pertains to a drug dispensed to a patient of that 340B covered entity. A pharmaceutical manufacturer may request that a 340B covered entity provide data that includes, without limitation, the following:

(1) the date of service that the 340B drug was dispensed;

(2) the date that the 340B drug was prescribed;

(3) the Rx number, also known as a prescription number, which is a unique identifier that a pharmacy assigns to each specific prescription filled or provided for a patient;

(4) the fill number for each 340B drug provided to a patient, which shall indicate whether that specific instance is the original or a subsequent fill of that particular container;

(5) the National Drug Code (NDC) number for the 340B drug dispensed, as used by the United States Food and Drug and published in the NDC Directory;

(6) the quantity of the 340B drugs dispensed;

(7) the appropriate prescriber ID or National Provider Identifier (NPI), which shall be the unique number identifying the health care provider who wrote the 340B drug prescription;

(8) the service provider ID or pharmacy/dispensing ID;

(9) the appropriate National Provider Identifier (NPI) or the National Council for Prescription Drug Programs

(NCPDP) provider ID for each filled prescription;

(10) the pharmacy BIN (Bank Identification Number) used to route electronic prescription claims to the correct entities for dispensed 340B drugs; and

(11) the Pharmacy Control Number (PCN) associated with each fill or refill of a 340B drug.

Section 25. Rulemaking. The Department shall adopt rules to implement this Act.

Section 30. Repeal. This Act is repealed on January 1, 2031.

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