25.1047.01000-Koppelman Amendments

HOUSE BILL NO. 1473

Sixty-ninth Legislative Assembly of North Dakota

Introduced by

Representatives Nelson, Mitskog, Murphy, Bahl, O'Brien

Senators Axtman, Dever, Lee

- 1 A BILL for an Act to create and enact a new subsection to section 43-15.3-08 of the North
- 2 Dakota Century Code, relating to prohibited acts of drug manufacturers; and to provide a
- 3 penalty.

4 BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

- 5 SECTION 1. A new subsection to section 43-15.3-08 of the North Dakota Century Code is
- 6 created and enacted as follows:
 - <u>a</u> For purposes of this subsection:
 - (1) <u>"340B savings" means the difference between (i) aggregated payments received</u> from insurers, third-party payers, or self-paying patients for all 340B drugs, and (ii) aggregated acquisition cost paid for all 340B drugs.
 - (2) <u>"340B program" means the federal drug pricing program described in 42 U.S.C.</u> <u>256b.</u>
 - (3) <u>"Contract pharmacy" means a pharmacy with which a covered entity has</u> <u>contracted to dispense 340B drugs on behalf of the covered entity to patients of</u> <u>the covered entity, whether distributed in person, via mail, or other means.</u>
 - (4) <u>"Low-income patient" means a patient of the covered entity with a family income below 200 percent of the Federal Poverty Guidelines,</u>
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 8 (1) "Contract pharmacy" means a pharmacy that has a contract with a covered 9 entity to receive and dispense drugs to the covered entity's patients on its.
 10 <u>behalf.</u>
 11 (2)(6) "Covered entity" means an entity participating or authorized to participate in a federal drug discount program under 42 U.S.C. 256b.
 (3)(7) "340B Drug" means a drug purchased under reduced pricing under section 340B of the federal Public Health Service Act [42 U.S.C. 201 et seq.] by a covered entity.

12	<u>b.</u>	Exc	ept as otherwise provided under section 43-15.3-09, it is a class B	
13		misdemeanor for a manufacturer, an agent or affiliate of that manufacturer, virtual		
14		mar	nufacturer, or third-party logistics provider of a manufacturer's drugs, to:	
15		<u>(1)</u>	Directly or indirectly deny, restrict, prohibit, or otherwise interfere with the	
16			acquisition of a drug by a contract pharmacy on behalf of a covered entity	
17			unless receipt of the drug is prohibited by federal law.	
18		<u>(2)</u>	Prohibit a contract pharmacy from dispensing a drug by denying access to	
		•	the drug.	
2		<u>(3)</u>	Require a covered entity or contract pharmacy to submit any claims,	
3			encounter, or utilization data as a condition for acquiring or receiving a drug,	
4			unless the claims, encounter, or utilization data sharing is required by	
5			federal law.	
6		<u>(4)</u>	Interfere with the ability of a covered entity or contract pharmacy to	
7			dispense a drug to an eligible patient of the covered entity.	
8		<u>(5)</u>	Offer or otherwise make available a drug in the form of a rebate, unless in	
9			the form of a discount at the time of sale and authorized under federal law.	
10	<u>C.</u>	<u>This</u>	subsection does not apply to the limited distribution of a drug as required	
11		under 21 U.S.C. 355-1.		
12			his subsection shall only apply with respect to physical contract pharmacy locations orth Dakota.	

SECTION 2.

- a. <u>Beginning on July 1, 2026, and by July 1 each year thereafter, each covered entity</u> <u>shall report to the department of health and human services with respect to the</u> <u>covered entity the following information about the prior year, in a form and manner</u> <u>determined by the department of health and human services:</u>
 - 1) <u>Delineated by form of insurance or third-party payer type, including but not</u> <u>limited to Medicaid, Medicare, commercial insurance, and uninsured:</u>
 - (a) <u>Aggregated acquisition costs paid for all 340B drugs, i.e., the metric</u> <u>that was used to calculate 340B savings;</u>
 - (b) <u>Aggregated payments received from insurers or third-party payers as</u> well as for self-paying patients for all 340B drugs, i.e., the metric that was used to calculate 340B savings;
 - (c) <u>Total number of prescriptions and the percentage of the covered</u> <u>entity's prescriptions that were filled with 340B drugs; and</u>
 - (d) <u>Percentage of patients served by a sliding fee scale for 340B drugs</u> <u>at the point of sale for low-income patients;</u>
 - 2) Total payments made to:

- (a) <u>Contract pharmacies for 340B program-related services and other</u> <u>functions;</u>
- (b) <u>Third-party administrators for managing any components of the</u> <u>covered entity's 340B program; and</u>
- (c) <u>Any other third parties in connection with 340B program-related</u> <u>compliance, legal, educational, and/or administrative costs;</u>
- 3) Total number of contract pharmacies, and
 - (a) <u>Number of contract pharmacies located out-of-state and the states in</u> which out-of-state contract pharmacies are located;
 - (b) <u>Total number of prescriptions and the percentage of the covered</u> <u>entity's prescriptions that were filled at contract pharmacies,</u> <u>delineated by in-state and out-of-state contract pharmacies;</u>
 - (c) <u>Total remuneration paid to or retained by contract pharmacies or</u> <u>their affiliates for any 340B program-related services performed on</u> <u>behalf of the covered entity; and</u>
 - (d) <u>The percentage change in subsection (2)(d)(3) of this section</u> <u>compared to the prior year;</u>
- b. An officer of the covered entity shall certify the completeness and accuracy of the report submitted pursuant to subsection (2) of this section.
- c. <u>The department of health and human services shall use the information described in</u> <u>subsection (2) of this section to prepare a report detailing aggregate information</u> <u>received from the covered entity, including 340B program revenue across all covered</u> <u>entities in the state. The department of health and human services shall submit this</u> <u>report to the Legislature by October 1, 2026. The department of health and human</u> <u>services shall post the report submitted to the legislative assembly and all reports</u> <u>submitted by covered entities pursuant to this section on a publicly accessible</u> <u>website.</u>".

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