21.0006.02000

Sixty-seventh
Legislative Assembly
of North Dakota

BILL NO.

Introduced by

Representative Keiser

A BILL for an Act to create and enact a new chapter to title 19 of the North Dakota Century Code, relating to prescription drug cost transparency; and to provide a penalty.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. A new chapter to title 19 of the North Dakota Century Code is created and enacted as follows:

Definitions.

As used in this chapter:

1. "Board" means the state board of pharmacy.
2. "Commissioner" means the insurance commissioner.
3. "Concession" includes a free good, delayed billing, and billing forgiveness.
4. "Drug" means an:
   a. Article recognized in the official United States pharmacopoeia, official homeopathic pharmacopoeia of the United States, or official national formulary;
   b. Article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in a human or other animal;
   c. Article, other than food, intended to affect the structure or any function of the body of a human or any other animal; or
   d. Article intended for use as a component of any article specified in this subsection; but does not include a device or component, part, or accessory of the device.
5. "Health care plan" means an individual, blanket, or group plan, policy, or contract for health care services issued or delivered in this state by a health insurer.
6. "Health insurer" means an insurance company, nonprofit health service corporation, health maintenance organization, third-party payer, health program administered by a

state agency, or other person engaged as principal in the business of insurance which issues or delivers a health care plan in this state.

7. "Net spending" means the cost of drugs minus any discounts that lower the price of the drugs, including a rebate, fee, retained price protection, retail pharmacy network spread, and dispensing fee.

8. "Pharmacy benefits manager" has the same meaning as provided under section 19-03.6-01.

9. "Rebate" means any discount, financial incentive, or concession that affects the price of a drug to a pharmacy benefits manager or health insurer for a drug manufactured by the pharmaceutical manufacturer.

10. "Specialty drug" has the same meaning as provided under section 19-02.1-16.2.

11. "Utilization management" means a set of formal techniques designed to monitor the use of, or evaluate the medical necessity, appropriateness, efficacy, or efficiency of, health care services, procedures, or settings.

12. "Wholesale acquisition cost" means, with respect to a drug, the manufacturer's list price for the drug to wholesalers or direct purchasers in the United States for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug pricing data, such as Medi-Span Price Rx or First Databank drug data. The term does not include a rebate, prompt pay, or other discount or other reduction in price.

NOTE: This bill draft creates duties for the State Board of Pharmacy. As an alternative, those same duties could be assigned to the Insurance Commissioner and Insurance Department.

Disclosure of drug pricing information.

1. a. Each drug manufacturer shall submit a report to the board no later than the fifteenth day of January, April, July, and October with the current wholesale acquisition cost information for the United States food and drug administration-approved drugs sold in or into the state by that manufacturer.

b. The board shall develop a website to publish wholesale acquisition cost information submitted under this subsection. The board shall make the website available on the board's website with a dedicated link prominently displayed on the home page, or by a separate, easily identifiable internet address.

2. a. Not more than thirty days after an increase in wholesale acquisition cost of forty percent or greater over the preceding five calendar years or ten percent or greater in the preceding twelve months for a drug with a wholesale acquisition cost of seventy dollars or more for a manufacturer-packaged drug container, a drug manufacturer shall submit a report to the board. The report must contain the following information:

(1) Name of the drug;

(2) Whether the drug is a brand name or a generic;

(3) The effective date of the change in wholesale acquisition cost;

(4) Aggregate, company-level research and development costs for the previous calendar year;

(5) Aggregate rebate amounts paid to each pharmacy benefits manager for the calendar year;

(6) The name of each of the manufacturer's drugs approved by the United States food and drug administration in the previous five calendar years;

(7) The name of each of the manufacturer's drugs that lost patent exclusivity in the United States in the previous five calendar years; and

(8) A statement of rationale regarding the factor or factors that caused the increase in the wholesale acquisition cost, such as raw ingredient shortage or increase in pharmacy benefits manager rebates.

b. The quality and types of information and data a drug manufacturer submits to the board pursuant to this subsection must be the same as the quality and types of information and data the manufacturer includes in the manufacturer's annual consolidated report on securities and exchange commission form 10-K or any other public disclosure.

c. Within sixty days of receipt, the board shall publish the report on the board's prescription drug price information website developed under this chapter.

3. A drug manufacturer shall notify the board in writing if the manufacturer is introducing a new drug to market at a wholesale acquisition cost that exceeds the threshold set for a specialty drug under the Medicare part D program.

a. The notice must include a statement of rationale regarding the factor or factors that caused the new drug to exceed the Medicare part D program price.

b. The drug manufacturer shall provide the written notice within three calendar days following the release of the drug in the commercial market.

c. A drug manufacturer may make the notification pending approval by the United States food and drug administration if commercial availability is expected within three calendar days following the approval.

Disclosure of pharmacy benefits manager information.

1. By February 1, 2022, and annually thereafter, a pharmacy benefits manager providing services for a health care plan shall file a report with the board. The report must contain the following information for the previous calendar year:

   a. The aggregated rebates, fees, price protection payments, and any other payments collected from each drug manufacturer;

   b. The aggregated dollar amount of rebates, price protection payments, fees, and any other payments collected from each drug manufacturer which were passed to health insurers;

   c. The aggregated fees, price concessions, penalties, effective rates, and any other financial incentive collected from pharmacies which were passed to enrollees at the point of sale; and

   d. The aggregated dollar amount of rebates, price protection payments, fees, and any other payments collected from drug manufacturers which were retained as revenue by the pharmacy benefits manager.

2. Reports submitted by pharmacy benefits managers under this section may not disclose the identity of a specific health benefit plan or enrollee, the prices charged for specific drugs or classes of drugs, or the amount of any rebates or fees provided for specific drugs or classes of drugs.

3. Within sixty days of receipt, the board shall publish the report on the board's prescription drug price information website developed under this chapter.

Disclosure of health insurer spending information.

1. a. By February 1, 2022, and annually thereafter, each health insurer shall submit a report to the board. The report must contain the following information for the previous two calendar years:
   (1) Names of the twenty-five most frequently prescribed drugs across all plans;
   (2) Names of the twenty-five drugs dispensed with the highest dollar spend in terms of gross revenue;
   (3) Percent increase in annual net spending for drugs across all plans;
   (4) Percent increase in premiums which is attributable to drugs across all plans;
   (5) Percentage of specialty drugs with utilization management requirements across all plans; and
   (6) Premium reductions attributable to specialty drug utilization management.

   b. Within sixty days of receipt, the board shall publish the report on the board's prescription drug price information website developed under this chapter.

2. A report submitted by a health insurer may not disclose the identity of a specific health benefit plan or the prices charged for specific drugs or classes of drugs.

Rulemaking - Forms.

1. The board may adopt rules to implement this chapter.
2. The board shall develop forms that must be used for reporting required under this chapter. The commissioner shall assist the board in developing forms for health insurer reporting required under this chapter.

Penalty.

A health care plan, drug manufacturer, or pharmacy benefits manager that violates this chapter is guilty of a class B misdemeanor.