21.0006.06004

Sixty-seventh
Legislative Assembly
of North Dakota

Introduced by

Legislative Management

(Health Care Committee)

FIRST ENGROSSMENT

ENGROSSED HOUSE BILL NO. 1032

A BILL for an Act to create and enact a new chapter to title ~~19~~26.1 of the North Dakota Century Code, relating to prescription drug cost transparency; to amend and reenact section 43-15.3-12 of the North Dakota Century Code, relating to wholesale drug license fees; to provide a continuing appropriation; 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:~~

SECTION 1. A new chapter to title 26.1 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" has the same meaning as provided under section 19-02.1-01.
5. "Drug manufacturer" means the entity that holds the national drug code for a drug which is engaged in the production, preparation, propagation, compounding, conversion, or processing of the drug or which is engaged in the packaging, repackaging, labeling, relabeling, or distribution of the drug. The term does not include a wholesale drug distributor or retail pharmacy licensed in this state.
6. "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.~~7. "Health insurer" means an insurance company, nonprofit health service corporation, health maintenance organization, third-party payer, health program administered by a

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

~~7. "Hospital" means a facility licensed under chapter 23-16.~~

8. "Manufacturer-packaged drug container" means a drug manufacturer-prepared supply of medication packaged in a container with a unique product-identifying national drug code number.

9. "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.

~~10. "Pharmacy" means a pharmacy or drugstore registered under chapter 43-15.~~

~~11.~~10. "Pharmacy benefits manager" has the same meaning as provided under section 19-03.6-01. The term does not include the department of human services or state department of health.

~~12. "Pharmacy services administrative organization" means an entity that provides contracting and other administrative services to a pharmacy to assist the pharmacy in the pharmacy's interaction, including reimbursement rate negotiations with a third-party payer, pharmacy benefit manager, wholesale drug distributor, and other entities.~~

~~13.~~11. "Prescription drug" ~~means a:~~

~~a. Substance for which federal or state law requires a prescription before the substance may be legally dispensed to the public;~~

~~b. Drug or device that under federal law is required, before being dispensed or delivered, to be labeled with the statement:~~

~~(1) "Caution: federal law prohibits dispensing without prescription" or "Rx only" or other legend that complies with federal law; or~~

~~(2) "Caution: federal law restricts this drug to use by or on the order of a licensed veterinarian"; or~~

~~c. Drug or device required by federal or state law to be dispensed on prescription or restricted to use by a practitioner~~has the same meaning as under section 43-15-01.

~~14.~~12. "Rebate" includes 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~~drug manufacturer.

~~15.~~13. "Specialty drug" has the same meaning as provided under section 19-02.1-16.2.

~~16.~~14. "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.

~~17.~~15. "Wholesale acquisition cost" means, with respect to a prescription drug, the drug manufacturer's list price for the prescription drug to ~~wholesale drug distributors~~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, Gold Standard Drug Database, or First Databank drug data. The term does not include a rebate, prompt pay, or other discount or other reduction in price.

~~18. "Wholesale drug distributor" has the same meaning as provided under section 43-15.1-01.~~

Disclosure of drug pricing information.

1. Each drug manufacturer shall submit a report to the ~~board~~commissioner 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~~prescription drugs sold in or into the state by that drug manufacturer.

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 prescription 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~~commissioner. 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 previous calendar year;

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

(8) A concise 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~~commissioner pursuant to this subsection must be the same as the quality and types of information and data the drug manufacturer includes in the drug manufacturer's annual consolidated report on securities and exchange commission form 10-K or any other public disclosure.

3. A drug manufacturer shall notify the ~~board~~commissioner in writing if the drug manufacturer is introducing a new prescription 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 concise 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.

~~4. Within thirty days of receipt of a report under this section, the board shall provide the reported information to the commissioner in a format ready for publication on the commissioner's website.~~

Disclosure of pharmacy benefits manager information.

1. On or before April first of each year, a pharmacy benefits manager providing services for a health care plan shall file a report with the ~~board~~commissioner. 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;
   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; and
   e. The aggregated rebates passed on to employers.
2. Reports submitted by pharmacy benefits managers under this section may not disclose the identity of a specific health benefit plan or enrollee, the identity of a drug manufacturer, 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 thirty days of receipt of a report under this section, the board shall provide the reported information to the commissioner in a format ready for publication on the commissioner's website. The information the board provides to the commissioner may not disclose or tend to disclose proprietary or confidential information of any pharmacy benefit manager.~~

Disclosure of health insurer spending information.

1. ~~a.~~ On or before April first of each year, each health insurer shall submit a report to the ~~board~~commissioner. The report must contain the following information for the previous two calendar years:
   ~~(1)~~a. Names of the twenty-five most frequently prescribed drugs across all plans;

~~(2)~~b. Names of the twenty-five prescription drugs dispensed with the highest dollar spend in terms of gross revenue;

~~(3)~~c. Percent increase in annual net spending for prescription drugs across all plans;

~~(4)~~d. Percent increase in premiums which is attributable to prescription drugs across all plans;

~~(5)~~e. Percentage of specialty drugs with utilization management requirements across all plans; and

~~(6)~~f. Premium reductions attributable to specialty drug utilization management.

~~b. Within thirty days of receipt of a report under this section, the board shall provide the reported information to the commissioner in a format ready for publication on the commissioner's website. The combined aggregated data from the reports which the board provides to the commissioner must be provided in a manner that does not disclose or tend to disclose proprietary or confidential information of any health insurer.~~

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 prescription drugs or classes of prescription drugs.

~~**Disclosure of pharmacy services administrative organization information.**~~

~~1. On or before April first of each year, a pharmacy services administrative organization providing services for a pharmacy 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 or wholesale drug distributor;~~

~~b. The aggregated dollar amount of rebates, price protection payments, fees, and any other payments collected from each drug manufacturer or wholesale drug distributor which were passed to pharmacies;~~

~~c. The aggregated fees, price concessions, penalties, effective rates, and any other financial incentive collected from pharmacies which were passed to pharmacies 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 or wholesale drug distributors which were retained as revenue by the pharmacy services administrative organization.~~

~~2. A report submitted by a pharmacy services administrative organization under this section may not disclose the identity of a specific health benefit plan or enrollee or the prices charged for specific drugs or classes of drugs.~~

~~3. Within thirty days of receipt of a report under this section, the board shall provide the reported information to the commissioner in a format ready for publication on the commissioner's website. The information the board provides to the commissioner may not disclose or tend to disclose proprietary or confidential information of any pharmacy services administrative organization.~~

~~**Disclosure of wholesale drug distributor information.**~~

~~1. On or before April first of each year, a wholesale drug distributor in this state 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;~~

~~c. The aggregated fees, price concessions, penalties, effective rates, and any other financial incentive collected from pharmacies;~~

~~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 wholesale drug distributor; and~~

~~e. The aggregated rebates passed on to employers.~~

~~2. Reports submitted by wholesale drug distributors 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 thirty days of receipt of a report under this section, the board shall provide the reported information to the commissioner in a format ready for publication on the commissioner's website. The information the board provides to the commissioner may not disclose or tend to disclose proprietary or confidential information of any wholesale drug distributor.~~

~~**Disclosure of hospital and pharmacy information.**~~

~~1. On or before April first of each year, a pharmacy and a hospital 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 for a pharmacy benefits manager;~~

~~b. The aggregated dollar amount of rebates, price protection payments, fees, and any other payments collected from each drug manufacturer or pharmacy benefits manager which were retained as revenue by the pharmacy or hospital; and~~

~~c. The aggregated rebates passed on to employers.~~

~~2. Reports submitted by a pharmacy or hospital 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 thirty days of receipt of a report under this section, the board shall provide the reported information to the commissioner in a format ready for publication on the commissioner's website. The information the board provides to the commissioner may not disclose or tend to disclose proprietary or confidential information of any pharmacy or hospital.~~

Website.

1. The commissioner shall develop a website to publish information ~~the board reports to~~ the commissioner receives under this chapter. The commissioner shall make the website available on the commissioner's website with a dedicated link prominently displayed on the home page, or by a separate, easily identifiable internet address.
2. Within ~~thirty~~sixty days of receipt of reported information ~~from the board~~under this chapter, the commissioner shall publish the reported information on the website

developed under this section. The information the commissioner publishes may not disclose or tend to disclose trade secret, proprietary, commercial, financial, or confidential information of any pharmacy, pharmacy benefits manager, drug wholesaler, or hospital.

Rulemaking - Forms - Services - Records.

1. The ~~board and the~~ commissioner may adopt rules to implement this chapter.
2. In consultation with the ~~commissioner~~board, the ~~board~~commissioner shall develop forms that must be used for reporting required under this chapter.
3. The ~~board~~commissioner may contract for services to implement this chapter.
4. A report received by the ~~board~~commissioner is an exempt record as defined by section 44-04-17.1; however, as provided under section 44-04-18.4 any portion of a report which discloses trade secret, proprietary, commercial, or financial information is confidential if it is of a privileged nature and has not been previously publicly disclosed.

Drug pricing fund - Transfer - Continuing appropriation.

The board may deposit up to six hundred dollars of every wholesaler license fee and every virtual wholesaler license fee collected by the board under section 43-15.3-12 to the drug pricing fund. All moneys in the fund, not otherwise appropriated, are appropriated to the insurance department to implement this chapter.

Civil penalty.

A health ~~care plan~~insurer, drug manufacturer, ~~hospital, pharmacy, wholesale drug distributor, pharmacy services administrative organization,~~ or pharmacy benefits manager that violates this chapter is subject to the imposition by the attorney general of a civil penalty not to exceed ten thousand dollars for each violation. The attorney general may waive or reduce a fine under this section upon a finding of good cause, such as excusable neglect or other extenuating circumstances. The fine may be collected and recovered in an action brought in the name of the state.

SECTION 2. AMENDMENT. Section 43-15.3-12 of the North Dakota Century Code is amended and reenacted as follows:

43-15.3-12. Fees.

The board shall charge and collect the following fees under this chapter:

Chain drug warehouse	$200
Chain pharmacy warehouse	$200
Durable medical equipment distributor, medical gas distributor, or both	$200
Durable medical equipment retailer, medical gas retailer and distributor, or both	$300
Hospital offsite warehouse	$200
Jobber or broker	~~$400~~Not to exceed $1,000
Manufacturer	~~$400~~Not to exceed $1,000
Medical gas retailer, durable medical equipment retailer, or both	$200
Medical gas durable medical equipment distributor and retailer	$300
Outsourcing facility	$200
Own label distributor	~~$400~~Not to exceed $1,000
Pharmacy distributor	$200
Private label distributor	~~$400~~Not to exceed $1,000
Repackager	~~$400~~Not to exceed $1,000
Reverse distributor	$200
Third-party logistic provider	~~$400~~Not to exceed $1,000
Veterinary-only distributor	$200
Virtual manufacturer	$400
Virtual wholesaler or distributor	~~$400~~Not to exceed $1,000
Wholesaler or distributor	~~$400~~Not to exceed $1,000