

Sixty-seventh
Legislative Assembly
of North Dakota

ENGROSSED HOUSE BILL NO. 1032

Introduced by

Legislative Management
(Health Care Committee)

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

5 **BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:**

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

8 **SECTION 1.** A new chapter to title 26.1 of the North Dakota Century Code is created and
9 enacted as follows:

10 **Definitions.**

11 As used in this chapter:

- 12 1. "Board" means the state board of pharmacy.
- 13 2. "Commissioner" means the insurance commissioner.
- 14 3. "Concession" includes a free good, delayed billing, and billing forgiveness.
- 15 4. "Drug" has the same meaning as provided under section 19-02.1-01.
- 16 5. "Drug manufacturer" means the entity that holds the national drug code for a drug
17 which is engaged in the production, preparation, propagation, compounding,
18 conversion, or processing of the drug or which is engaged in the packaging,
19 repackaging, labeling, relabeling, or distribution of the drug. The term does not include
20 a wholesale drug distributor or retail pharmacy licensed in this state.
- 21 6. "Health care plan" means an individual, blanket, or group plan, policy, or contract for
22 health care services issued or delivered in this state by a health insurer.
- 23 ~~6.7.~~ "Health insurer" means an insurance company, nonprofit health service corporation,
24 health maintenance organization, third-party payer, health program administered by a

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

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

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

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

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

12 ~~11.10.~~ "Pharmacy benefits manager" has the same meaning as provided under section
13 19-03.6-01. The term does not include the department of human services or state
14 department of health.

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

20 ~~13.11.~~ "Prescription drug" means a:

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

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

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

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

29 ~~c. Drug or device required by federal or state law to be dispensed on prescription or~~
30 ~~restricted to use by a practitioner~~ has the same meaning as under section
31 43-15-01.

1 ~~14.12.~~ "Rebate" includes any discount, financial incentive, or concession that affects the price
2 of a drug to a pharmacy benefits manager or health insurer for a drug manufactured
3 by the ~~pharmaceutical~~drug manufacturer.

4 ~~15.13.~~ "Specialty drug" has the same meaning as provided under section 19-02.1-16.2.

5 ~~16.14.~~ "Utilization management" means a set of formal techniques designed to monitor the
6 use of, or evaluate the medical necessity, appropriateness, efficacy, or efficiency of,
7 health care services, procedures, or settings.

8 ~~17.15.~~ "Wholesale acquisition cost" means, with respect to a prescription drug, the drug
9 manufacturer's list price for the prescription drug to ~~wholesale drug-~~
10 ~~distributors~~wholesalers or direct purchasers in the United States for the most recent
11 month for which the information is available, as reported in wholesale price guides or
12 other publications of drug pricing data, such as Medi-Span Price Rx, Gold Standard
13 Drug Database, or First Databank drug data. The term does not include a rebate,
14 prompt pay, or other discount or other reduction in price.

15 ~~18.~~ ~~"Wholesale drug distributor" has the same meaning as provided under section~~
16 ~~43-15.1-01.~~

17 **Disclosure of drug pricing information.**

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

22 2. a. Not more than thirty days after an increase in wholesale acquisition cost of forty
23 percent or greater over the preceding five calendar years or ten percent or
24 greater in the preceding twelve months for a prescription drug with a wholesale
25 acquisition cost of seventy dollars or more for a manufacturer-packaged drug
26 container, a drug manufacturer shall submit a report to the ~~board~~commissioner.

27 The report must contain the following information:

28 (1) Name of the drug;

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

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

- 1 (4) Aggregate, company-level research and development costs for the previous
2 calendar year;
- 3 (5) Aggregate rebate amounts paid to each pharmacy benefits manager for the
4 previous calendar year;
- 5 (6) The name of each of the drug manufacturer's drugs approved by the United
6 States food and drug administration in the previous five calendar years;
- 7 (7) The name of each of the drug manufacturer's drugs that lost patent
8 exclusivity in the United States in the previous five calendar years; and
- 9 (8) A concise statement of rationale regarding the factor or factors that caused
10 the increase in the wholesale acquisition cost, such as raw ingredient
11 shortage or increase in pharmacy benefits manager rebates.
- 12 b. The quality and types of information and data a drug manufacturer submits to the
13 board commissioner pursuant to this subsection must be the same as the quality
14 and types of information and data the drug manufacturer includes in the drug
15 manufacturer's annual consolidated report on securities and exchange
16 commission form 10-K or any other public disclosure.
- 17 3. A drug manufacturer shall notify the board commissioner in writing if the drug
18 manufacturer is introducing a new prescription drug to market at a wholesale
19 acquisition cost that exceeds the threshold set for a specialty drug under the Medicare
20 part D program.
- 21 a. The notice must include a concise statement of rationale regarding the factor or
22 factors that caused the new drug to exceed the Medicare part D program price.
- 23 b. The drug manufacturer shall provide the written notice within three calendar days
24 following the release of the drug in the commercial market.
- 25 c. A drug manufacturer may make the notification pending approval by the United
26 States food and drug administration if commercial availability is expected within
27 three calendar days following the approval.
- 28 ~~4. Within thirty days of receipt of a report under this section, the board shall provide the~~
29 ~~reported information to the commissioner in a format ready for publication on the~~
30 ~~commissioner's website.~~

1 **Disclosure of pharmacy benefits manager information.**

2 1. On or before April first of each year, a pharmacy benefits manager providing services
3 for a health care plan shall file a report with the ~~board~~commissioner. The report must
4 contain the following information for the previous calendar year:

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

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

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

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

16 e. The aggregated rebates passed on to employers.

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

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

26 **Disclosure of health insurer spending information.**

27 1. a. ~~—~~ On or before April first of each year, each health insurer shall submit a report to
28 the ~~board~~commissioner. The report must contain the following information for the
29 previous two calendar years:

30 ~~(1)~~a. Names of the twenty-five most frequently prescribed drugs across all
31 plans;

- 1 —~~(2)~~b. Names of the twenty-five prescription drugs dispensed with the highest
2 dollar spend in terms of gross revenue;
- 3 —~~(3)~~c. Percent increase in annual net spending for prescription drugs across all
4 plans;
- 5 —~~(4)~~d. Percent increase in premiums which is attributable to prescription drugs
6 across all plans;
- 7 —~~(5)~~e. Percentage of specialty drugs with utilization management requirements
8 across all plans; and
- 9 —~~(6)~~f. Premium reductions attributable to specialty drug utilization management.
- 10 —~~b.~~ Within thirty days of receipt of a report under this section, the board shall provide
11 the reported information to the commissioner in a format ready for publication on
12 the commissioner's website. The combined aggregated data from the reports
13 which the board provides to the commissioner must be provided in a manner that
14 does not disclose or tend to disclose proprietary or confidential information of any
15 health insurer.
- 16 2. A report submitted by a health insurer may not disclose the identity of a specific health
17 benefit plan or the prices charged for specific prescription drugs or classes of
18 prescription drugs.
- 19 —**Disclosure of pharmacy services administrative organization information.**
- 20 —~~1.~~ On or before April first of each year, a pharmacy services administrative organization
21 providing services for a pharmacy shall file a report with the board. The report must
22 contain the following information for the previous calendar year:
- 23 —~~a.~~ The aggregated rebates, fees, price protection payments, and any other
24 payments collected from each drug manufacturer or wholesale drug distributor;
- 25 —~~b.~~ The aggregated dollar amount of rebates, price protection payments, fees, and
26 any other payments collected from each drug manufacturer or wholesale drug
27 distributor which were passed to pharmacies;
- 28 —~~c.~~ The aggregated fees, price concessions, penalties, effective rates, and any other
29 financial incentive collected from pharmacies which were passed to pharmacies
30 at the point of sale; and

- 1 ~~d. The aggregated dollar amount of rebates, price protection payments, fees, and~~
2 ~~any other payments collected from drug manufacturers or wholesale drug~~
3 ~~distributors which were retained as revenue by the pharmacy services~~
4 ~~administrative organization.~~
- 5 ~~2. A report submitted by a pharmacy services administrative organization under this~~
6 ~~section may not disclose the identity of a specific health benefit plan or enrollee or the~~
7 ~~prices charged for specific drugs or classes of drugs.~~
- 8 ~~3. Within thirty days of receipt of a report under this section, the board shall provide the~~
9 ~~reported information to the commissioner in a format ready for publication on the~~
10 ~~commissioner's website. The information the board provides to the commissioner may~~
11 ~~not disclose or tend to disclose proprietary or confidential information of any pharmacy~~
12 ~~services administrative organization.~~
- 13 ~~**Disclosure of wholesale drug distributor information.**~~
- 14 ~~1. On or before April first of each year, a wholesale drug distributor in this state shall file a~~
15 ~~report with the board. The report must contain the following information for the~~
16 ~~previous calendar year:~~
- 17 ~~a. The aggregated rebates, fees, price protection payments, and any other~~
18 ~~payments collected from each drug manufacturer;~~
- 19 ~~b. The aggregated dollar amount of rebates, price protection payments, fees, and~~
20 ~~any other payments collected from each drug manufacturer;~~
- 21 ~~c. The aggregated fees, price concessions, penalties, effective rates, and any other~~
22 ~~financial incentive collected from pharmacies;~~
- 23 ~~d. The aggregated dollar amount of rebates, price protection payments, fees, and~~
24 ~~any other payments collected from drug manufacturers which were retained as~~
25 ~~revenue by the wholesale drug distributor; and~~
- 26 ~~e. The aggregated rebates passed on to employers.~~
- 27 ~~2. Reports submitted by wholesale drug distributors under this section may not disclose~~
28 ~~the identity of a specific health benefit plan or enrollee, the prices charged for specific~~
29 ~~drugs or classes of drugs, or the amount of any rebates or fees provided for specific~~
30 ~~drugs or classes of drugs.~~

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

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

7 ~~1. On or before April first of each year, a pharmacy and a hospital shall file a report with~~
8 ~~the board. The report must contain the following information for the previous calendar~~
9 ~~year:~~

10 ~~a. The aggregated rebates, fees, price protection payments, and any other~~
11 ~~payments collected for a pharmacy benefits manager;~~

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

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

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

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

25 **Website.**

26 1. The commissioner shall develop a website to publish information ~~the board reports to~~
27 ~~the commissioner~~ receives under this chapter. The commissioner shall make the
28 website available on the commissioner's website with a dedicated link prominently
29 displayed on the home page, or by a separate, easily identifiable internet address.

30 2. Within ~~thirty~~sixty days of receipt of reported information ~~from the board~~under this
31 ~~chapter~~, the commissioner shall publish the reported information on the website

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

5 **Rulemaking - Forms - Services - Records.**

- 6 1. The ~~board and the~~ commissioner may adopt rules to implement this chapter.
7 2. In consultation with the ~~commissioner~~board, the ~~board~~commissioner shall develop
8 forms that must be used for reporting required under this chapter.
9 3. The ~~board~~commissioner may contract for services to implement this chapter.
10 4. A report received by the ~~board~~commissioner is an exempt record as defined by section
11 44-04-17.1; however, as provided under section 44-04-18.4 any portion of a report
12 which discloses trade secret, proprietary, commercial, or financial information is
13 confidential if it is of a privileged nature and has not been previously publicly
14 disclosed.

15 **Drug pricing fund - Transfer - Continuing appropriation.**

16 There is created in the state treasury the drug pricing fund, which consists of any money
17 deposited in the fund by the board and any interest earned on moneys in the fund. The board
18 may deposit up to six hundred dollars of every wholesaler license fee and every virtual
19 wholesaler license fee collected by the board under section 43-15.3-12 to the drug pricing fund.
20 All moneys in the fund, not otherwise appropriated, are appropriated to the insurance
21 department to implement this chapter.

22 **Civil penalty.**

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

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

1	43-15.3-12. Fees.	
2	The board shall charge and collect the following fees under this chapter:	
3	Chain drug warehouse	\$200
4	Chain pharmacy warehouse	\$200
5	Durable medical equipment distributor, medical gas distributor, or both	\$200
6	Durable medical equipment retailer, medical gas retailer and distributor, or both	\$300
7	Hospital offsite warehouse	\$200
8	Jobber or broker	\$400 <u>Not to exceed \$1,000</u>
9	Manufacturer	\$400 <u>Not to exceed \$1,000</u>
10	Medical gas retailer, durable medical equipment retailer, or both	\$200
11	Medical gas durable medical equipment distributor and retailer	\$300
12	Outsourcing facility	\$200
13	Own label distributor	\$400 <u>Not to exceed \$1,000</u>
14	Pharmacy distributor	\$200
15	Private label distributor	\$400 <u>Not to exceed \$1,000</u>
16	Repackager	\$400 <u>Not to exceed \$1,000</u>
17	Reverse distributor	\$200
18	Third-party logistic provider	\$400 <u>Not to exceed \$1,000</u>
19	Veterinary-only distributor	\$200
20	Virtual manufacturer	\$400
21	Virtual wholesaler or distributor	\$400 <u>Not to exceed \$1,000</u>
22	Wholesaler or distributor	\$400 <u>Not to exceed \$1,000</u>