

Introduced by

Legislative Management

(Health Care Committee)

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

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

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

6 **Definitions.**

7 As used in this chapter:

8 1. "Board" means the state board of pharmacy.

9 2. "Commissioner" means the insurance commissioner.

10 3. "Concession" includes a free good, delayed billing, and billing forgiveness.

11 4. "Drug" has the same meaning as provided under section 19-02.1-01.

12 5. "Health care plan" means an individual, blanket, or group plan, policy, or contract for  
13 health care services issued or delivered in this state by a health insurer.

14 6. "Health insurer" means an insurance company, nonprofit health service corporation,  
15 health maintenance organization, third-party payer, health program administered by a  
16 state agency, or other person engaged as principal in the business of insurance which  
17 issues or delivers a health care plan in this state.

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

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

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

- 1        10. "Pharmacy" means a pharmacy or drugstore registered under chapter 43-15.
- 2        11. "Pharmacy benefits manager" has the same meaning as provided under section  
3        19-03.6-01.
- 4        12. "Pharmacy services administrative organization" means an entity that provides  
5        contracting and other administrative services to a pharmacy to assist the pharmacy in  
6        the pharmacy's interaction, including reimbursement rate negotiations with a  
7        third-party payer, pharmacy benefit manager, wholesale drug distributor, and other  
8        entities.
- 9        13. "Prescription drug" means a:
- 10       a. Substance for which federal or state law requires a prescription before the  
11       substance may be legally dispensed to the public;
- 12       b. Drug or device that under federal law is required, before being dispensed or  
13       delivered, to be labeled with the statement:
- 14           (1) "Caution: federal law prohibits dispensing without prescription" or "Rx only"  
15           or other legend that complies with federal law; or
- 16           (2) "Caution: federal law restricts this drug to use by or on the order of a  
17           licensed veterinarian"; or
- 18       c. Drug or device required by federal or state law to be dispensed on prescription or  
19       restricted to use by a practitioner.
- 20       14. "Rebate" includes any discount, financial incentive, or concession that affects the price  
21       of a drug to a pharmacy benefits manager or health insurer for a drug manufactured  
22       by the pharmaceutical manufacturer.
- 23       15. "Specialty drug" has the same meaning as provided under section 19-02.1-16.2.
- 24       16. "Utilization management" means a set of formal techniques designed to monitor the  
25       use of, or evaluate the medical necessity, appropriateness, efficacy, or efficiency of,  
26       health care services, procedures, or settings.
- 27       17. "Wholesale acquisition cost" means, with respect to a prescription drug, the  
28       manufacturer's list price for the prescription drug to wholesale drug distributors or  
29       direct purchasers in the United States for the most recent month for which the  
30       information is available, as reported in wholesale price guides or other publications of  
31       drug pricing data, such as Medi-Span Price Rx, Gold Standard Drug Database, or First

1           Databank drug data. The term does not include a rebate, prompt pay, or other  
2           discount or other reduction in price.

3       18.   "Wholesale drug distributor" has the same meaning as provided under section  
4           43-15.1-01.

5       **Disclosure of drug pricing information.**

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

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

16           (1)   Name of the drug;

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

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

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

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

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

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

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

30      b.   The quality and types of information and data a drug manufacturer submits to the  
31           board pursuant to this subsection must be the same as the quality and types of

1 information and data the manufacturer includes in the manufacturer's annual  
2 consolidated report on securities and exchange commission form 10-K or any  
3 other public disclosure.

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

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

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

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

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

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

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

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

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

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

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

- 1           e. The aggregated rebates passed on to employers.
- 2           2. Reports submitted by pharmacy benefits managers under this section may not  
3           disclose the identity of a specific health benefit plan or enrollee, the prices charged for  
4           specific drugs or classes of drugs, or the amount of any rebates or fees provided for  
5           specific drugs or classes of drugs.
- 6           3. Within thirty days of receipt of a report under this section, the board shall provide the  
7           reported information to the commissioner in a format ready for publication on the  
8           commissioner's website. The information the board provides to the commissioner may  
9           not disclose or tend to disclose proprietary or confidential information of any pharmacy  
10          benefit manager.

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

- 12          1. a. On or before April first of each year, each health insurer shall submit a report to  
13             the board. The report must contain the following information for the previous two  
14             calendar years:
- 15             (1) Names of the twenty-five most frequently prescribed drugs across all plans;  
16             (2) Names of the twenty-five prescription drugs dispensed with the highest  
17             dollar spend in terms of gross revenue;  
18             (3) Percent increase in annual net spending for prescription drugs across all  
19             plans;  
20             (4) Percent increase in premiums which is attributable to prescription drugs  
21             across all plans;  
22             (5) Percentage of specialty drugs with utilization management requirements  
23             across all plans; and  
24             (6) Premium reductions attributable to specialty drug utilization management.
- 25          b. Within thirty days of receipt of a report under this section, the board shall provide  
26             the reported information to the commissioner in a format ready for publication on  
27             the commissioner's website. The combined aggregated data from the reports  
28             which the board provides to the commissioner must be provided in a manner that  
29             does not disclose or tend to disclose proprietary or confidential information of any  
30             health insurer.

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

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

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

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

- 29      1. On or before April first of each year, a wholesale drug distributor in this state shall file a  
30      report with the board. The report must contain the following information for the  
31      previous calendar year:

- 1           a. The aggregated rebates, fees, price protection payments, and any other  
2           payments collected from each drug manufacturer;
- 3           b. The aggregated dollar amount of rebates, price protection payments, fees, and  
4           any other payments collected from each drug manufacturer;
- 5           c. The aggregated fees, price concessions, penalties, effective rates, and any other  
6           financial incentive collected from pharmacies;
- 7           d. The aggregated dollar amount of rebates, price protection payments, fees, and  
8           any other payments collected from drug manufacturers which were retained as  
9           revenue by the wholesale drug distributor; and
- 10          e. The aggregated rebates passed on to employers.
- 11         2. Reports submitted by wholesale drug distributors under this section may not disclose  
12         the identity of a specific health benefit plan or enrollee, the prices charged for specific  
13         drugs or classes of drugs, or the amount of any rebates or fees provided for specific  
14         drugs or classes of drugs.
- 15         3. Within thirty days of receipt of a report under this section, the board shall provide the  
16         reported information to the commissioner in a format ready for publication on the  
17         commissioner's website. The information the board provides to the commissioner may  
18         not disclose or tend to disclose proprietary or confidential information of any wholesale  
19         drug distributor.

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

- 21         1. On or before April first of each year, a pharmacy and a hospital shall file a report with  
22         the board. The report must contain the following information for the previous calendar  
23         year:
  - 24           a. The aggregated rebates, fees, price protection payments, and any other  
25           payments collected for a pharmacy benefits manager;
  - 26           b. The aggregated dollar amount of rebates, price protection payments, fees, and  
27           any other payments collected from each drug manufacturer or pharmacy benefits  
28           manager which were retained as revenue by the pharmacy or hospital; and
  - 29           c. The aggregated rebates passed on to employers.
- 30         2. Reports submitted by a pharmacy or hospital under this section may not disclose the  
31         identity of a specific health benefit plan or enrollee, the prices charged for specific

1 drugs or classes of drugs, or the amount of any rebates or fees provided for specific  
2 drugs or classes of drugs.  
3 3. Within thirty days of receipt of a report under this section, the board shall provide the  
4 reported information to the commissioner in a format ready for publication on the  
5 commissioner's website. The information the board provides to the commissioner may  
6 not disclose or tend to disclose proprietary or confidential information of any pharmacy  
7 or hospital.

8 **Website.**

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

15 **Rulemaking - Forms - Services - Records.**

16 1. The board and the commissioner may adopt rules to implement this chapter.  
17 2. In consultation with the commissioner, the board shall develop forms that must be  
18 used for reporting required under this chapter.  
19 3. The board may contract for services to implement this chapter.  
20 4. A report received by the board is an exempt record as defined by section 44-04-17.1.

21 **Civil penalty.**

22 A health care plan, drug manufacturer, hospital, pharmacy, wholesale drug distributor,  
23 pharmacy services administrative organization, or pharmacy benefits manager that violates this  
24 chapter is subject to the imposition by the attorney general of a civil penalty not to exceed  
25 ten thousand dollars for each violation. The fine may be collected and recovered in an action  
26 brought in the name of the state.