

Introduced by

Senator Anderson

Representative M. Nelson

1 A BILL for an Act to create and enact chapter 19-03.7 of the North Dakota Century Code,
2 relating to prescription drug costs; and to provide a penalty.

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

4 **SECTION 1.** Chapter 19-03.7 of the North Dakota Century Code is created and enacted as
5 follows:

6 **19-03.7-01. Definitions.**

7 As used in this chapter:

- 8 1. "Employee Retirement Income Security Act plan" means a plan qualified under the
9 federal Employee Retirement Income Security Act of 1974 [29 U.S.C. 1002 et seq.].
- 10 2. "Health plan" has the same meaning as accident and health insurance policy under
11 section 26.1-36-02.
- 12 3. "Participating Employee Retirement Income Security Act plan" means an Employee
13 Retirement Income Security Act plan that has elected to participate in the
14 requirements and restrictions of this chapter as described in section 19-03.7-03.
- 15 4. "Prescription drug" has the same meaning as stated in section 43-15.1-01.
- 16 5. "Referenced drugs" means prescription drugs subject to a referenced rate.
- 17 6. "Referenced rate" means the maximum rate established by the insurance
18 commissioner utilizing the wholesale acquisition cost and other pricing data described
19 in section 19-03.7-04.
- 20 7. "State entity" means any agency of state government that purchases prescription
21 drugs on behalf of the state for an individual whose health care is paid for by the state,
22 including any agent, vendor, fiscal agent, contractor, or other party acting on behalf of
23 the state. The term does not include the medical assistance program established
24 under 42 U.S.C. section 1396 et seq.

1 8. "Wholesale acquisition cost" has the meaning stated in 42 U.S.C. section 1395w-3a.

2 **19-03.7-02. Payment in excess of referenced rate prohibited.**

3 1. It is a violation of this chapter for a state entity, health plan, or participating Employee
4 Retirement Income Security Act plan to purchase referenced drugs to be dispensed or
5 delivered to a consumer in the state, whether directly or through a distributor, for a
6 cost higher than the referenced rate as determined in section 19-03.7-04.

7 2. It is a violation of this chapter for a retail pharmacy licensed in this state to purchase
8 for sale or distribution referenced drugs for a cost that exceeds the referenced rate to
9 an individual whose health care is provided by a state entity, health plan, or
10 participating Employee Retirement Income Security Act plan.

11 **19-03.7-03. Employee Retirement Income Security Act plan opt-in.**

12 An Employee Retirement Income Security Act plan may elect to participate in the provisions
13 of this chapter. Any Employee Retirement Income Security Act plan that desires its purchase of
14 prescription drugs to be subject to the prohibition described in section 19-03.7-02 shall notify
15 the insurance commissioner in writing by October first of each year.

16 **19-03.7-04. Referenced drugs determined.**

17 1. As of October first of each year, on a form established by the insurance commissioner,
18 the public employees retirement system shall transmit to the insurance commissioner
19 a list of the most costly prescription drugs based upon net price times utilization. For
20 each of these prescription drugs, the public employees retirement system also shall
21 provide the total net spend on each of those prescription drugs for the previous
22 calendar year.

23 2. Utilizing the information described in subsection 1, as of January first of each year, the
24 insurance commissioner shall create and publish a list of the referenced drugs subject
25 to the referenced rate. The insurance commissioner shall identify the number of
26 reference drugs subject to the referenced rate.

27 3. The insurance commissioner shall establish a rate to be used as a basis to begin
28 negotiation. The insurance commissioner shall establish this rate by comparing the
29 wholesale acquisition cost to reference costs such as the cost from the Ontario
30 ministry of health and long-term care and most recently published on the Ontario Drug
31 Benefit Formulary; régie de l'assurance maladie du Québec and most recently

1 published on the Quebec Public Drug Programs List of Medications; British Columbia
2 ministry of health and most recently published on the BC PharmaCare Formulary; and
3 Alberta ministry of health and most recently published on the Alberta Drug Benefit List.
4 If a specific referenced drug is not included within the identified resources, the
5 insurance commissioner may utilize as a reference for the purpose of determining the
6 rate used as a basis to begin negotiation, the ceiling price for drugs as reported by the
7 government of Canada patented medicine prices review board.

8 4. The insurance commissioner shall negotiate with manufacturers and distributors of
9 referenced drugs to set a reference rate for each of the identified drugs.

10 5. The insurance commissioner shall calculate annually the savings expected to be
11 achieved by subjecting prescription drugs to the referenced rate. In making this
12 determination the commissioner shall consult with the public employees retirement
13 system and the state board of pharmacy.

14 6. The insurance commissioner may adopt rules to implement fully the requirements of
15 this chapter.

16 **19-03.7-05. Registered agent.**

17 An entity that sells, distributes, delivers, or offers for sale any prescription drug in the state
18 must have a registered agent in the state.

19 **19-03.7-06. Use of savings - Referenced drug fund.**

20 1. A health plan or participating Employee Retirement Income Security Act plan shall use
21 any savings generated as a result of the requirements in section 19-03.7-02 to reduce
22 costs to their members. A health plan or participating Employee Retirement Income
23 Security Act plan shall calculate the savings and utilize the savings directly to reduce
24 costs for its members. No later than April first of each year, each health plan and
25 participating Employee Retirement Income Security Act plan subject to this chapter
26 shall submit a report to the insurance commissioner describing the savings achieved
27 for each referenced drug for the previous calendar year and how those savings were
28 used to reduce costs to its members.

29 2. A state entity shall deposit any savings generated as a result of the requirements in
30 section 19-03.7-02 into a referenced drug fund in the state treasury. Subject to
31 legislative appropriation, the money in the fund must be used by the public employees

1 retirement system and the insurance commissioner to administer this chapter and to
2 reduce health plan premiums of state entities.

3 **19-03.7-07. Enforcement - Penalty.**

4 Each violation of this chapter is subject to a fine of one thousand dollars. Every individual
5 transaction in violation of section 19-03.7-02 is determined to be a separate violation. The
6 attorney general may enforce this chapter on behalf of any state entity or consumers of
7 prescription drugs. The insurance commissioner and state board of pharmacy shall work with
8 the attorney general in enforcing this chapter. The refusal of a manufacturer or distributor to
9 negotiate in good faith as described in subsection 4 of section 19-03.7-08 is a valid affirmative
10 defense in any enforcement action brought under this chapter.

11 **19-03.7-08. Prohibition on withdrawal of referenced drugs for sale - Penalty.**

- 12 1. It is a violation of this chapter for a manufacturer or distributor of a referenced drug to
13 withdraw the referenced drug from sale or distribution within this state for the purpose
14 of avoiding the impact of the rate limitations set forth in section 19-03.7-02.
- 15 2. A manufacturer that intends to withdraw a referenced drug from sale or distribution
16 from within the state shall provide a notice of withdrawal in writing to the insurance
17 commissioner, to the state board of pharmacy, and to the attorney general at least one
18 hundred eighty days before the withdrawal.
- 19 3. The insurance commissioner shall assess a penalty on a manufacturer or distributor
20 that the insurance commissioner, working in consultation with the state board of
21 pharmacy, determines has withdrawn a referenced drug from distribution or sale in the
22 state in violation of subsection 1 or 2. With respect to each referenced drug for which
23 the insurance commissioner has determined the manufacturer or distributor has
24 withdrawn from the market, the penalty must be equal to five hundred thousand dollars
25 or the amount of annual savings determined by the insurance commissioner as
26 described in subsection 5 of section 19-03.7-04, whichever is greater.
- 27 4. It is a violation of this chapter for a manufacturer or distributor of a referenced drug to
28 refuse to negotiate in good faith with a payor or seller of prescription drugs a price that
29 is within the referenced rate as determined in section 19-03.7-04.
- 30 5. The insurance commissioner shall assess a penalty on a manufacturer or distributor
31 the insurance commissioner, working in consultation with the state board of pharmacy.

1 determines has failed to negotiate in good faith in violation of subsection 4. With
2 respect to each referenced drug for which the insurance commissioner has
3 determined the manufacturer or distributor has failed to negotiate in good faith, the
4 penalty must be equal to five hundred thousand dollars or the amount of annual
5 savings determined by the insurance commissioner as described in subsection 5 of
6 section 19-03.7-04, whichever is greater.