21.0611.01001

Sixty-seventh
Legislative Assembly
of North Dakota

SENATE BILL NO. 2170

Introduced by

Senator Anderson

Representative M. Nelson

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

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

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

19-03.7-01. Definitions.

As used in this chapter:

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

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

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

1. It is a violation of this chapter for a state entity, health plan, or participating Employee Retirement Income Security Act plan to purchase referenced drugs to be dispensed or delivered to a consumer in the state, whether directly or through a distributor, for a cost higher than the referenced rate as determined in section 19-03.7-04.
2. It is a violation of this chapter for a retail pharmacy licensed in this state to purchase for sale or distribution referenced drugs for a cost that exceeds the referenced rate to an individual whose health care is provided by a state entity, health plan, or participating Employee Retirement Income Security Act plan.

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

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

19-03.7-04. Referenced drugs determined.

1. As of October first of each year, on a form established by the insurance commissioner, the public employees retirement system shall transmit to the insurance commissioner a list of the ~~two hundred fifty~~ most costly prescription drugs based upon net price times utilization. For each of these prescription drugs, the public employees retirement system also shall provide the total net spend on each of those prescription drugs for the previous calendar year.
2. Utilizing the information described in subsection 1, as of January first of each year, the insurance commissioner shall create and publish a list of ~~two hundred fifty~~the referenced drugs subject to the referenced rate. The insurance commissioner shall identify the number of reference drugs subject to the referenced rate.
3. The insurance commissioner shall ~~determine the referenced rate~~establish a rate to be used as a basis to begin negotiation. The insurance commissioner shall establish this rate by comparing the wholesale acquisition cost to reference costs such as the cost from the Ontario ministry of health and long-term care and most recently published on the Ontario Drug Benefit Formulary; régie de l'assurance maladie du Québec and

most recently published on the Quebec Public Drug Programs List of Medications; British Columbia ministry of health and most recently published on the BC PharmaCare Formulary; and Alberta ministry of health and most recently published on the Alberta Drug Benefit List.

~~4. The referenced rate for each prescription drug must be calculated as the lowest cost among those resources and the wholesale acquisition cost.~~ If a specific referenced drug is not included within the identified resources ~~described in subsection 3~~, the insurance commissioner ~~shall~~may utilize as a reference for the purpose of determining the ~~referenced~~ rate ~~a reference such as~~used as a basis to begin negotiation, the ceiling price for drugs as reported by the government of Canada patented medicine prices review board.

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

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

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

19-03.7-05. Registered agent ~~and office within the state~~.

An entity that sells, distributes, delivers, or offers for sale any prescription drug in the state must ~~be~~have a registered agent ~~and maintain an office within~~in the state.

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

1. ~~Any~~A health plan or participating Employee Retirement Income Security Act plan shall use any savings generated as a result of the requirements in section 19-03.7-02 ~~must be used~~ to reduce costs to ~~consumers~~their members. A ~~state entity,~~ health plan~~,~~ or participating Employee Retirement Income Security Act plan shall calculate the savings and utilize the savings directly to reduce costs for its members.

~~2.~~ No later than April first of each year, each ~~state entity,~~ health plan~~,~~ and participating Employee Retirement Income Security Act plan subject to this chapter shall submit a report to the insurance commissioner describing the savings achieved for each

referenced drug for the previous calendar year and how those savings were used to ~~achieve the requirements of subsection 1~~reduce costs to its members.

2. A state entity shall deposit any savings generated as a result of the requirements in section 19-03.7-02 into a referenced drug fund in the state treasury. Subject to legislative appropriation, the money in the fund must be used by the public employees retirement system and the insurance commissioner to administer this chapter and to reduce health plan premiums of state entities.

19-03.7-07. Enforcement - Penalty.

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

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

1. It is a violation of this chapter for a manufacturer or distributor of a referenced drug to withdraw the referenced drug from sale or distribution within this state for the purpose of avoiding the impact of the rate limitations set forth in section 19-03.7-02.
2. A manufacturer that intends to withdraw a referenced drug from sale or distribution from within the state shall provide a notice of withdrawal in writing to the insurance commissioner, to the state board of pharmacy, and to the attorney general at least one hundred eighty days before the withdrawal.
3. The insurance commissioner shall assess a penalty on a manufacturer or distributor that the insurance commissioner, working in consultation with the state board of pharmacy, determines has withdrawn a referenced drug from distribution or sale in the state in violation of subsection 1 or 2. With respect to each referenced drug for which the insurance commissioner has determined the manufacturer or distributor has withdrawn from the market, the penalty must be equal to five hundred thousand dollars or the amount of annual savings determined by the insurance commissioner as described in subsection 5 of section 19-03.7-04, whichever is greater.

4. It is a violation of this chapter for a manufacturer or distributor of a referenced drug to refuse to negotiate in good faith with a payor or seller of prescription drugs a price that is within the referenced rate as determined in section 19-03.7-04.

5. The insurance commissioner shall assess a penalty on a manufacturer or distributor the insurance commissioner, working in consultation with the state board of pharmacy, determines has failed to negotiate in good faith in violation of subsection 4. With respect to each referenced drug for which the insurance commissioner has determined the manufacturer or distributor has failed to negotiate in good faith, the penalty must be equal to five hundred thousand dollars or the amount of annual savings determined by the insurance commissioner as described in subsection 45 of section 19-03.7-04, whichever is greater.