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S T A T E O F R H O D E I S L A N D

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2021

A N A C T

RELATING TO FOOD AND DRUGS -- PRESCRIPTION DRUG COST PROTECTION

Introduced By: Representatives Tanzi, Potter, Morales, Ajello, Ranglin-Vassell, Fogarty, Kislak, Cortvriend, Batista, and Hull
Date Introduced: February 24, 2021

Referred To: House Health & Human Services

It is enacted by the General Assembly as follows:

SECTION 1. Title 21 of the General Laws entitled "FOOD AND DRUGS" is hereby amended by adding thereto the following chapter:

CHAPTER 38

PRESCRIPTION DRUG COST PROTECTION

21-38-1. Definitions.

For the purposes of this chapter:

(1) "ERISA plan" means a plan qualified under the Employee Retirement Income Security Act of 1974.

(2) "Health plan" means health insurance coverage or a plan providing coverage pursuant to the provision of chapters 18.5, 18.6, 19 and 20 of title 27.

(3) "Participating ERISA plan" means an ERISA plan that has elected to participate in the requirements and restrictions of this chapter as described in § 21-38-3.

(4) "Prescription drug" or "drug" has the same meaning as the term "drug" as defined in § 5-19.1-2.

(5) "Referenced drugs" means prescription drugs subjected to a referenced rate.

(6) "Referenced rate" means the maximum rate established by the superintendent of insurance utilizing the wholesale acquisition cost and other pricing data pursuant to § 21-38-4.

(7) "State entity" means any agency of state government that purchases prescription drugs on behalf of the state for a person 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. State entity does not include the medical assistance program established under 42 U.S.C. § 1396 et seq.

(8) "Wholesale acquisition cost" means, with respect to a drug or biological, the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

21-38-2. Payment in excess of referenced rate -- prohibited.

(a) It is a violation of this chapter for a state entity or health plan or participating ERISA 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 § 21-38-4.

(b) 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 a person whose health care is provided by a state entity or health plan or participating ERISA plan.

21-38-3. ERISA plan opt-in.

An ERISA plan may elect to participate in the provisions of this chapter. Any ERISA plan that desires its purchase of prescription drugs to be subject to the prohibition described in § 21-38-2 shall notify the superintendent of insurance in writing by February 1 of each year.

21-38-4. Referenced drugs determined.

(a) As of March 1 of each calendar year, the director of the state employee health insurance plan shall transmit to the superintendent of insurance a list of the two hundred fifty (250) most costly prescription drugs based upon net price multiplied utilization. For each of these prescription drugs, the director of the state employee health insurance plan shall also provide the total net spend on each of those prescription drugs for the previous calendar year.

(b) Utilizing this information provided in subsection (a) of this section, as of May 1 of each calendar year the superintendent of insurance shall create and publish a list of two hundred fifty (250) referenced drugs that shall be subject to the referenced rate.

(c) The superintendent of insurance shall determine the referenced rate by comparing the wholesale acquisition cost to the cost from the:

(1) Ontario ministry of health and long-term care and most recently published on the Ontario drug benefit formulary;

(2) Régie de L'Assurance Maladie du Québec and most recently published on the Québec public drug programs list of medications.

(3) British Columbia ministry of health and most recently published on the British Columbia pharmacare formulary; and

(4) Alberta ministry of health and most recently published on the Alberta drug benefit list.

(d) The referenced rate for each prescription drug shall be calculated as the lowest cost among those resources and the wholesale acquisition cost. If a specific referenced drug is not included within resources described in subsection (c) of this section, the superintendent of insurance shall utilize for the purpose of determining the referenced rate ceiling price for drugs as reported by the government of Canada patented medicine prices review board.

(e) The superintendent of insurance shall calculate annually the savings that are expected to be achieved by subjecting prescription drugs to the referenced rate. In making this determination the superintendent of insurance shall consult with the director of the state employee health insurance plan and the chair of the state board of pharmacy.

(f) The superintendent of insurance shall have the authority to promulgate regulations under § 42-14-5 to fully implement the requirements of this chapter.

21-38-5. Registered agent and office within the state.

Any entity that sells, distributes, delivers or offers for sale any prescription drug in the state shall be required to maintain a registered agent and office within the state.

21-38-6. Use of savings.

(a) Any savings generated as a result of implementation and compliance with the provisions of this chapter shall be used to reduce costs to consumers. Any state entity, health plan or participating ERISA plan shall calculate such savings and utilize such savings directly to reduce costs for its members.

(b) No later than April 1 of each calendar year, each state entity, health plan and participating ERISA plan subject to this chapter shall submit to the superintendent of insurance a report describing the savings achieved for each referenced drug for the previous calendar year and how those savings were used to achieve the requirements of lower cost prescription prices.

21-38-7. Prohibition on withdrawal of referenced drugs for sale.

(a) It shall be a violation of this chapter for any manufacturer or distributor of a referenced drug to withdraw that drug from sale or distribution within this state for the purpose of avoiding the impact of the rate limitations set forth in § 21-38-2.

(b) Any 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 superintendent of insurance and to the attorney general one hundred eighty (180) days prior to withdrawal.

(c) The superintendent of insurance shall assess a penalty on any manufacturer or

distributor that it determines has withdrawn a referenced drug from distribution or sale in the state in violation of § 21-38-7(a). With respect to each referenced drug for which the superintendent of insurance has determined the manufacturer or distributor has withdrawn from the market, the penalty shall be equal to five hundred thousand dollars ($500,000) or the amount of annual savings determined by the superintendent of insurance as described in § 21-38-4(e), whichever is greater.

(d) It shall be a violation of this chapter for any manufacturer or distributor of a referenced drug to refuse to negotiate in good faith with any payer or seller of prescription drugs a price that is within the referenced rate as determined in §21-38-4.

(e) The superintendent of insurance shall assess a penalty on any manufacturer or distributor that it determines has failed to negotiate in good faith in violation of subsection (d) of this section. With respect to each referenced drug for which the superintendent of insurance has determined the manufacturer or distributor has failed to negotiate in good faith, the penalty shall be equal to five hundred thousand dollars ($500,000) or the amount of annual savings determined by the superintendent of insurance as described in § 21-38-4(e), whichever is greater.

21-38-8. Enforcement.

(a) Each violation of § 21-38-2 shall be subject to a fine of one thousand dollars ($1,000). Every individual transaction in violation of § 21-38-2 is determined to be a separate violation.

(b) The attorney general is authorized to enforce the provisions of this statute on behalf of any state entity or consumers of prescription drugs. The refusal of a manufacturer or distributor to negotiate in good faith as described in § 21-38-7(d) shall be a valid affirmative defense in any enforcement action for a violation of § 21-38-2.

21-38-9. Severability.

If any provision of this chapter or its application to any person or circumstances is held invalid, the invalidity shall not affect other provisions or applications of the chapter which can be given effect without the invalid provision or application, and to this end the provisions of this chapter are declared to be severable.

SECTION 2. This act shall take effect upon passage.

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EXPLANATION

BY THE LEGISLATIVE COUNCIL

OF

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RELATING TO FOOD AND DRUGS -- PRESCRIPTION DRUG COST PROTECTION

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This act would prohibit the state, participating ERISA or any health plan from purchasing referenced drugs for a cost higher than the referenced rate. The referenced rate will have two hundred fifty (250) of the most costly prescription drugs based upon the net price multiplied by utilization and the referenced rate shall be determined by comparing wholesale acquisition cost to the cost from various Canadian drug lists. Any manufacturer or distributor who fails to comply with the purchase standards shall be subject to a penalty equal to five hundred thousand dollars ($500,000) or the amount of annual savings determined by the superintendent, whichever if greater. Additionally, any manufacturer or distributor who fails to negotiate in good faith shall be subject to a penalty of five hundred thousand dollars ($500,000) or the amount of annual savings determined by the superintendent of insurance, whichever is greater.

This act would take effect upon passage.

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