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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. 2023

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A N A C T

RELATING TO STATE AFFAIRS AND GOVERNMENT -- THE RHODE ISLAND HEALTH CARE REFORM ACT OF 2004 -- HEALTH INSURANCE OVERSIGHT

Introduced By: Senators Lauria, DiPalma, Murray, Valverde, Euer, Miller, DiMario, Lawson, Ujifusa, and Pearson
Date Introduced: March 07, 2023

Referred To: Senate Health & Human Services

It is enacted by the General Assembly as follows:

SECTION 1. Chapter 42-14.5 of the General Laws entitled "The Rhode Island Health Care Reform Act of 2004 — Health Insurance Oversight" is hereby amended by adding thereto the following section:

42-14.5-6. Unsupported price increases on prescription drugs.

(a) Purpose. It is the purpose of this section to protect the safety, health and economic well-being of Rhode Island residents by guarding them against the negative and harmful impact of unsupported price increases for prescription drugs.

(b) Definitions. As used in this chapter, the following words and terms shall have the following meanings unless the context shall clearly indicate another or different meaning or intent:

(1) "Consumer price index" means the Consumer Price Index, Annual Average, for All Urban Consumers, (CPI-U): US City Average, all items, as reported by the United States Department of Labor, Bureau of Labor Statistics, or its successor or, if the index is discontinued, an equivalent index reported by a federal authority or, if no such index is reported, "consumer price index" means a comparable index chosen by the United States Bureau of Labor Statistics.

(2) "Identified drug" means any prescription drug that has at any time been identified as having an unsupported price increase.

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

(4) "Unsupported price increase" means an increase in price for a prescription drug for

which there was no, or inadequate, new clinical evidence to support the price increase. In order to determine whether a price increase for a prescription drug is unsupported by new clinical evidence, the state shall utilize and rely upon the analyses of prescription drugs prepared annually by the Institute for Clinical and Economic Review (ICER) and published in its annual Unsupported Price Increase Report.

(5) "Wholesale acquisition cost" means 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 as defined in 42 U.S.C. § 1395w-3 (a) (c) (6).

(c) Penalty imposed and collection power. A penalty shall be assessed on the sales within the state of identified drugs and payable by the manufacturers of the identified drugs. The penalty shall be calculated as described in subsection (c)(1) of this section.

(1) The penalty in any calendar year shall equal eighty percent (80%) of the difference between the revenue generated by sales within the state of the identified drugs and the revenue that would have been generated if the manufacturer had maintained the wholesale acquisition cost from the previous calendar year, adjusted for inflation utilizing the consumer price index.

(2) In order to be subject to the penalty, a manufacturer shall have at least two hundred fifty thousand dollars ($250,000) in total annual sales within the state in the calendar year for which the penalty is assessed.

(3) Within sixty (60) days of the annual publication by ICER of the Unsupported Price Increase Report, the commissioner shall identify the manufacturers of identified drugs. The commissioner shall notify each manufacturer that sales within the state of identified drugs shall be subject to the penalty assessed in this section for a period of two (2) calendar years following the identified drug's appearance in the annual publication by ICER.

(4) Penalty shall be collected annually. Any manufacturer notified by the commissioner pursuant to subsection (c)(3) of this section shall submit to the commissioner a return on a form prescribed and furnished by the commissioner and pay the penalty by April 15 for the previous calendar year.

(5) The form described in subsection (c)(4) of this section shall contain information including, but not limited to:

(i) The total amount of sales of the identified drug within the state;

(ii) The total number of units sold of the identified drug within the state;

(iii) The wholesale acquisition cost of the identified drug during the tax period and any

changes in the wholesale acquisition cost during the calendar year;

(iv) The wholesale acquisition cost during the previous calendar year;

(v) A calculation of the penalty owed; and

(vi) Any other information that the commissioner determines is necessary to calculate the correct amount of the penalty owed.

(6) The commissioner may request any department or agency to assist in calculation of the penalty and collection, including the tax administrator, who may collect the penalty amount owed with interest in the same manner and with the same powers as are prescribed for collection of taxes in title 44.

(d) Use of revenue.

(1) The payments required by this section shall be made by electronic transfer of monies to the general treasurer.

(2) The general treasurer shall take all steps necessary to facilitate the transfer of funds to a restricted receipt account and made available to the office of the health insurance commissioner to offset costs to assess and collect the penalty, audit manufacturers that are required to submit returns pursuant to this section and defend appeals from manufacturers. The balance shall be deposited equally to the "childhood immunization account" described in § 23-1-45(a) and the "adult immunization account" described in § 23-1-45(c).

(3) The general treasurer shall provide the commissioner with a record of any funds received and the director of the department of health with a record of any funds transferred and deposited into the two (2) immunization accounts pursuant to subsection (d)(2) of this section.

(e) Prohibition on withdrawal of prescription drugs for sale.

(1) Any manufacturer or distributor of an identified drug shall be prohibited from withdrawing that drug from sale or distribution within this state for the purpose of avoiding the penalty set forth in this section.

(2) Any manufacturer who intends to withdraw an identified drug from sale or distribution from within the state in order to avoid a penalty as described in this section shall provide a notice of withdrawal in writing to the state pharmacy board and the attorney general one hundred eighty days (180) days prior to such withdrawal.

(3) The commissioner shall assess a penalty of five hundred thousand dollars ($500,000) on any entity, including any manufacturer or distributor of an identified drug, that they determine has withdrawn an identified drug from distribution or sale in the state in violation of this section.

(f) Hearing by commissioner on application and appeals.

(1) Any manufacturer aggrieved by the action of the commissioner in determining the

amount of any penalty imposed under this section may apply to the commissioner, within thirty (30) days after the notice of the action is mailed, for a hearing. The commissioner shall fix a time and place for the hearing and shall so notify the manufacturer. Upon hearing, the commissioner shall correct manifest errors, if any, disclosed at the hearing and thereupon assess and collect the amount lawfully due together with any penalty or interest.

(2) Appeals from administrative orders or decisions made pursuant to any provision of this section shall be made pursuant to chapter 35 of title 42. The right to appeal under this section shall be expressly made conditional upon prepayment of all interest and penalties unless the manufacturer demonstrates, to the satisfaction of the court, that the manufacturer has a reasonable probability of success on the merits and is unable to prepay all interest and penalties, considering not only the manufacturer's own financial resources but also the ability of the manufacturer to borrow the required funds. If the court, after appeal, holds that the manufacturer is entitled to a refund, the manufacturer shall also be paid interest on the amount at the rate provided in § 44-1-7.1.

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 STATE AFFAIRS AND GOVERNMENT -- THE RHODE ISLAND HEALTH CARE REFORM ACT OF 2004 -- HEALTH INSURANCE OVERSIGHT

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This act would establish a process whereby large drug manufacturers (those earning at least two hundred fifty thousand dollars ($250,000) in total annual sales within the state) may be penalized for increasing prices for an identified prescription drug where there is no, or inadequate, evidence to support the price increase. The act would create a procedure where the commissioner would notify the manufacturer by way of a form that would contain the total amount of sales of the identified drug within the state, the total number of units sold of the identified drug within the state, the wholesale acquisition cost of the identified drug and any changes to that cost during the year and the previous year, a calculation of the penalty owed, and any other information that the commissioner deems necessary. The act would also provide an opportunity for the manufacturer to have a hearing and to appeal the decision rendered at that hearing.

This act would take effect upon passage.

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