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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 FOOD AND DRUGS -- PRESCRIPTION DRUG ADVISORY BOARD - GROUP PURCHASING BOARD FOR RX WE CAN AFFORD

Introduced By: Representatives McNamara, Potter, Donovan, Cotter, and Morales

Date Introduced: February 10, 2023

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 ADVISORY BOARD - GROUP PURCHASING BOARD FOR RX WE CAN AFFORD

21-38-1. Definitions.

The following words have the meanings indicated:

(1) "Biologic" or "biosimilar" means a drug that is produced or distributed in accordance with a biologics license application approved under 42 U.S.C. § 262(k)(3).

(2) "Board" means the prescription drug advisory board.

(3)(i) "Brand name drug" means a drug that is produced or distributed in accordance with an original new drug application approved under 21 U.S.C. § 355(c).

(ii) "Brand name drug" does not include an authorized generic as defined by 42 C.F.R. § 447.502.

(4) "Generic drug" means:

(i) A retail drug that is marketed or distributed in accordance with an abbreviated new drug application, approved under 21 U.S.C. § 355(j);

(ii) An authorized generic as defined by 42 C.F.R. § 447.502; or

(iii) A drug that entered the market before 1962 that was not originally marketed under a new drug application.

(5) "Manufacturer" means an entity that:

(i)(A) Engages in the manufacture of a prescription drug product; or

(B) Enters into a lease with another manufacturer to market and distribute a prescription drug product under the entity's own name; and

(ii) Sets or changes the wholesale acquisition cost of the prescription drug product it manufactures or markets.

(6) "Prescription drug product" means a brand name drug, a generic drug, a biologic, or a biosimilar.

21-38-2. Prescription drug advisory board established -- Purpose.

(a)(1) There is hereby established a prescription drug advisory board.

(2)(i) The board is a body politic and corporate and is an instrumentality of the state.

(ii) The board is an independent unit of state government.

(iii) The exercise by the board of its authority under this chapter is an essential governmental function.

(b) The purpose of the board is to protect state residents, state and local governments, commercial health plans, health care providers, pharmacies licensed in the state, and other stakeholders within the health care system from the high costs of prescription drug products.

21-38-3. Membership.

(a)(1) The board shall consist of the following five (5) members, who shall have expertise in health care economics or clinical medicine:

(i) One member appointed by the governor for an initial term of one year;

(ii) One member appointed by the president of the senate for an initial term of two (2) years;

(iii) One member appointed by the speaker of the house of representatives for an initial term of three (3) years;

(iv) One member appointed by the attorney general for an initial term of two (2) years; and

(v) One member appointed jointly by the president of the senate and the speaker of the house of representatives, who shall serve as chair of the board, for an initial term of three (3) years.

(2) The board shall have the following three (3) alternate members, who shall have expertise in health care economics or clinical medicine and who shall be designated by the board chair to participate in deliberations of the board when a member is recused:

(i) One alternate member appointed by the governor for an initial term of three (3) years;

(ii) One alternate member appointed by the president of the senate for an initial term of two (2) years; and

(iii) One alternate member appointed by the speaker of the house of representatives for an initial term of one year.

(3) A member or an alternate member may not be an employee of, a board member of, or a consultant to a manufacturer, pharmacy benefits manager, health insurance carrier, health maintenance organization, managed care organization, or wholesale distributor or related trade association.

(4) Any conflict of interest, including whether the individual has an association, including a financial or personal association, that has the potential to bias or has the appearance of biasing an individual's decision in matters related to the board or the conduct of the board's activities, shall be considered and disclosed when appointing members and alternate members to the board.

(5) To the extent practicable and consistent with federal and state law, the membership of the board shall reflect the racial, ethnic, and gender diversity of the state.

(b) The term of a member or an alternate member shall be three (3) years after the initial period of appointments. The terms of the members and alternate members shall be staggered as required by the provisions of this section.

(c) A member of the board is entitled to reimbursement for reasonable expenses incurred.

(d)(1)(i) Any chapter. The board shall meet in open session at least once every six (6) weeks.

(ii) At the chair's discretion, the chair may cancel or postpone a meeting.

(iii) The following actions by the board shall be made in open session:

(A) Deliberations on whether to subject a prescription drug product to a cost review under this chapter;

(B) Any vote on whether to recommend an upper payment limit on purchases and payor reimbursements of prescription drug products in the state; and

(C) Any decision by the board.

(iv) Notwithstanding chapter 46 of title 42, the ("open meetings"), the board may meet in closed session to discuss trade secrets or confidential and proprietary data and information.

(2) The board shall provide public notice of each board meeting at least two (2) weeks in advance of the meeting.

(3)(i) Materials for each board meeting shall be made available to the public at least one week in advance of the meeting.

(ii) Materials containing trade secrets or confidential and proprietary data or information

that is not otherwise available to the public shall not be made available to the public.

(4) The board shall provide an opportunity for public comment at each open meeting of the board.

(5) The board shall provide the public with the opportunity to provide written comments on pending decisions of the board.

(6) The board may allow expert testimony at board meetings, including when the board meets in closed session.

(7) To the extent practicable, the board shall access pricing information for prescription drug products by:

(i) Entering into a memorandum of understanding with another state to which manufacturers already report pricing information; and

(ii) Accessing other available pricing information.

(8) A majority of the members of the board shall constitute a quorum.

(9)(i) Members of the board shall recuse themselves from decisions related to a prescription drug product if the member, or an immediate family member of the member, has received or could receive any of the following:

(A) A direct financial benefit of any amount deriving from the result or finding of a study or determination by or for the board; or

(B) A financial benefit from any person that owns, manufactures, or provides prescription drug products, services, or items to be studied by the board that in the aggregate exceeds five thousand dollars ($5,000) per year.

(ii) For the purposes of this section, a financial benefit includes honoraria, fees, stock, the value of the member's or immediate family member's stock holdings, and any direct financial benefit deriving from the finding of a review conducted under this chapter.

(e) In addition to the powers set forth elsewhere in this chapter, the board may adopt rules and regulations to carry out the provisions of this chapter;

21-38-4. Severability.

If any provision of this chapter or the application thereof to any person or circumstances is held invalid, such 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 on January 1, 2024.

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EXPLANATION

BY THE LEGISLATIVE COUNCIL

OF

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RELATING TO FOOD AND DRUGS -- PRESCRIPTION DRUG ADVISORY BOARD - GROUP PURCHASING BOARD FOR RX WE CAN AFFORD

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This act would create a prescription drug advisory board composed of five (5) members and three (3) alternates with expertise in health care economics or clinical medicine designated to investigate and comprehensively evaluate drug prices for Rhode Islanders and possible ways to reduce them in order to make them more affordable.

This act would take effect on January 1, 2024.

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