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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. 2020

A N A C T

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

Introduced By: Representatives McNamara, Corvese, Hawkins, Shekarchi, and Jackson

Date Introduced: January 16, 2020

Referred To: House Health, Education & Welfare

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 AFFORDABILITY BOARD - GROUP PURCHASING BOARD FOR RX WE CAN AFFORD

21-38-1. Definitions.

The following words have the meanings indicated:

(1) "Biologic" means a drug that is produced or distributed in accordance with a biologics license application approved under 42 C.F.R. § 447.502.

(2) "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).

(3) "Board" means the prescription drug affordability board.

(4)(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.

(5) "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.

(6) "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.

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

(8) "Stakeholder council" means the prescription drug affordability stakeholder council.

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

(a)(1) There is hereby established a prescription drug affordability 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 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 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)(1) The chair shall hire an executive director, general counsel, and staff for the board.

(2) The chair shall develop a five (5) year budget and staffing plan and submit it to the board for approval.

(3) Staff of the board shall receive a salary as provided in the budget of the board.

(d) A member of the board:

(1) May receive compensation as a member of the board in accordance with the state budget; and

(2) Is entitled to reimbursement for reasonable expenses incurred.

(e)(1)(i) Notwithstanding the provisions of subsections (e)(1)(i) and (e)(1)(iv) of this section, 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) The study required by § 21-38-7;

(B) Deliberations on whether to subject a prescription drug product to a cost review under § 21-38-8 of this chapter;

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

(D) Any decision by the board.

(iv) Notwithstanding chapter 46 of title 42, the "open meetings act", 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 may 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 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.

(f) In addition to the powers set forth elsewhere in this chapter, the board may:

(1) Adopt rules and regulations to carry out the provisions of this chapter; and

(2) Enter into a contract with a qualified, independent third party for any service necessary to carry out the powers and duties of the board.

(g) Unless permission is granted by the board, a third party hired by the board in accordance with subsection (f)(2) of this section may not release, publish, or otherwise use any information to which the third party has access under its contract.

21-38-4. Prescription drug affordability stakeholder council established.

(a) There is hereby established a prescription drug affordability stakeholder council.

(b) The purpose of the stakeholder council is to provide stakeholder input to assist the board in making decisions as required under this chapter.

(c)(1) The stakeholder council shall consist of twenty-six (26) members appointed in accordance with this subsection.

(2) The speaker of the house of representatives shall appoint:

(i) One representative of generic drug corporations to an initial term of one year;

(ii) One representative of nonprofit insurance carriers to an initial term of two (2) years;

(iii) One representative of a statewide health care advocacy coalition to an initial term of three (3) years;

(iv) One representative of a statewide advocacy organization for seniors to an initial term of one year;

(v) One representative of a statewide organization for diverse communities to an initial term of two (2) years;

(vi) One representative of a labor union to an initial term of three (3) years;

(vii) One health services researcher specializing in prescription drugs to an initial term of one year; and

(viii) One public member at the discretion of the speaker of the house of representatives to an initial term of two (2) years.

(3) The president of the senate shall appoint:

(i) One representative of brand name drug corporations to an initial term of one year;

(ii) One representative of physicians to an initial term of two (2) years;

(iii) One representative of nurses to an initial term of three (3) years;

(iv) One representative of hospitals to an initial term of one year;

(v) One representative of dentists to an initial term of two (2) years;

(vi) One representative of managed care organizations to an initial term of three (3) years;

(vii) One representative of the department of administration's office of management and budget to an initial term of one year;

(viii) One clinical researcher to an initial term of two (2) years; and

(ix) One public member at the discretion of the president of the senate to an initial term of three (3) years.

(4) The governor shall appoint:

(i) One representative of brand name drug corporations to an initial term of three (3) years;

(ii) One representative of generic drug corporations to an initial term of two (2) years;

(iii) One representative of biotechnology companies to an initial term of one year;

(iv) One representative of for-profit health insurance carriers to an initial term of three (3) years;

(v) One representative of employers to an initial term of two (2) years;

(vi) One representative of pharmacy benefits managers to an initial term of one year;

(vii) One representative of pharmacists to an initial term of three (3) years;

(viii) One pharmacologist to an initial term of two (2) years; and

(ix) One public member at the discretion of the governor to an initial term of one year.

(5) Collectively, the members of the stakeholder council shall have knowledge of the following:

(i) The pharmaceutical business model;

(ii) Supply chain business models;

(iii) The practice of medicine or clinical training;

(iv) Consumer or patient perspectives;

(v) Health care costs trends and drivers;

(vi) Clinical and health services research; and

(vii) The state's health care marketplace.

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

(7) From among the membership of the stakeholder council, the board chair shall appoint two (2) members to be co-chairs of the stakeholder council.

(d) The term of a member shall be three (3) years after the initial period of appointments.

The initial members of the stakeholder council shall serve staggered terms as required by the provisions of this section.

(e) A member of the stakeholder council:

(1) May not receive compensation as a member of the stakeholder council; but

(2) Is entitled to reimbursement for expenses.

21-38-5. Disclosure of conflict of interest.

(a)(1) A conflict of interest shall be disclosed:

(i) By the board when hiring board staff;

(ii) By the appointing authority when appointing members and alternate members to the board and members to the stakeholder council; and

(iii) By the board, when a member of the board is recused in any final decision resulting from a review of a prescription drug product.

(2) A conflict of interest shall be disclosed:

(i) In advance of the first open meeting after the conflict is identified; or

(ii) Within five (5) days after the conflict is identified.

(b)(1) A conflict of interest disclosed under subsection (a) of this section shall be posted on the website of the board unless the chair of the board recuses the member from any final decision resulting from a review of a prescription drug product.

(2) A posting under this section shall include the type, nature, and magnitude of the interests of the member involved.

21-38-6. Acceptance of gifts of donations.

Members and alternate members of the board, board staff, and third-party contractors may not accept any gift or donation of services or property that indicates a potential conflict of interest or has the appearance of biasing the work of the board.

21-38-7. Study of aspects of pharmaceutical distribution and payment -- Report.

On or before December 31, 2021, the board, in consultation with the stakeholder council, shall:

(1) Study:

(i) The entire pharmaceutical distribution and payment system in the state; and

(ii) Policy options being used in other states and countries to lower the list price of pharmaceuticals, including:

(A) Setting upper payment limits;

(B) Using a reverse auction marketplace; and

(C) Implementing a bulk purchasing process; and

(2) Report its findings and recommendations, including findings for each option studied under subsection (1)(ii) of this section and any legislation required to implement the recommendations, to the senate finance committee and the house health, education and welfare committee.

21-38-8. Identifying prescription drug products that create affordability challenges for state health care system and patients.

(a) On or before December 31, 2021, the board shall:

(1) Collect and review publicly available information regarding prescription drug product manufacturers, health insurance carriers, health maintenance organizations, managed care organizations, wholesale distributors, and pharmacy benefits managers; and

(2)(i) Identify states that require reporting on the cost of prescription drug products; and

(ii) Initiate a process of entering into memoranda of understanding with the states identified under subsection (a)(2)(i) of this section to aid in the collection of transparency data for prescription drug products.

(b) Based on the information collected under subsection (a)(1) of this section and obtained through memoranda of understanding under subsection (a)(2) of this section, the board, in consultation with the stakeholder council, shall adopt rules and regulations to:

(1) Establish methods for collecting additional data necessary to carry out its duties under this chapter; and

(2) Identify circumstances under which the cost of a prescription drug product may create or has created affordability challenges for the state health care system and patients.

(c) The board shall use the information collected under subsection (a)(1) of this section and obtained through memoranda of understanding under subsection (a)(2) of this section to identify prescription drug products that are:

(1) Brand name drugs or biologics that, as adjusted annually for inflation in accordance with the consumer price index, have:

(i) A launch wholesale acquisition cost of thirty thousand dollars ($30,000) or more per year or course of treatment; or

(ii) A wholesale acquisition cost increase of three thousand ($3,000) or more in any twelve (12) month period, or course of treatment if less than twelve (12) months;

(2) Biosimilar drugs that have a launch wholesale acquisition cost that is not at least fifteen percent (15%) lower than the referenced brand biologic at the time the biosimilars are launched;

(3) Generic drugs that, as adjusted annually for inflation in accordance with the consumer

price index, have a wholesale acquisition cost:

(i) Of one hundred dollars ($100) or more for:

(A) A thirty (30) day supply lasting a patient for a period of thirty (30) consecutive days based on the recommended dosage approved for labeling by the United States Food and Drug Administration;

(B) A supply lasting a patient for fewer than thirty (30) days based on the recommended dosage approved for labeling by the United States Food and Drug Administration; or

(C) One unit of the drug if the labeling approved by the United States Food and Drug Administration does not recommend a finite dosage; and

(ii) That increased by two hundred percent (200%) or more during the immediately preceding twelve (12) month period, as determined by the difference between the resulting wholesale acquisition cost and the average of the wholesale acquisition cost reported over the immediately preceding twelve (12) months; and

(4) Other prescription drug products that may create affordability challenges for the state health care system and patients, in consultation with the stakeholder council.

21-38-9. Cost review of prescription drug products identified in § 21-38-8.

(a)(1) After identifying prescription drug products as required by § 21-38-8 of this chapter, the board shall determine whether to conduct a cost review as described in subsection (b) of this section for each identified prescription drug product by:

(i) Seeking stakeholder council input about the prescription drug product; and

(ii) Considering the average cost share of the prescription drug product.

(2)(i) To the extent there is no publicly available information to conduct a cost review as described in subsection (b) of this section, the board shall request the information from:

(A) The manufacturer of the prescription drug product; and

(B) As appropriate, a wholesale distributor, pharmacy benefits manager, health insurance carrier, health maintenance organization, or managed care organization with relevant information on setting the cost of the prescription drug product in the state.

(ii) The information to conduct a cost review may include any document and research related to the manufacturer's selection of the introductory price or price increase of the prescription drug product, including life cycle management, net average price in the state, market competition and context, projected revenue, and the estimated value or cost-effectiveness of the prescription drug product.

(iii) Failure of a manufacturer, wholesale distributor, pharmacy benefits manager, health insurance carrier, health maintenance organization, or managed care organization to provide the

board with the information requested under this subsection shall not affect the authority of the board to conduct a review as described in subsection (b) of this section.

(b)(1) If the board conducts a review of the cost of a prescription drug product, the review shall determine whether use of the prescription drug product that is fully consistent with the labeling approved by the United States Food and Drug Administration or standard medical practice has led or will lead to affordability challenges for the state health care system or high out-of-pocket costs for patients.

(2) To the extent practicable, in determining whether a prescription drug product identified under § 21-38-8 of this chapter has led or will lead to an affordability challenge, the board shall consider the following factors:

(i) The wholesale acquisition cost and any other relevant prescription drug cost index for the prescription drug product sold in the state;

(ii) The average monetary price concession, discount, or rebate the manufacturer provides to health plans in the state or is expected to provide to health plans in the state as reported by manufacturers and health plans, expressed as a percent of the wholesale acquisition cost for the prescription drug product under review;

(iii) The total amount of the price concession, discount, or rebate the manufacturer provides to each pharmacy benefits manager operating in the state for the prescription drug product under review, as reported by manufacturers and pharmacy benefits managers, expressed as a percent of the wholesale acquisition costs;

(iv) The price at which therapeutic alternatives have been sold in the state;

(v) The average monetary concession, discount, or rebate the manufacturer provides or is expected to provide to health plan payors and pharmacy benefits managers in the state for therapeutic alternatives;

(vi) The costs to health plans based on patient access consistent with United States Food and Drug Administration labeled indications;

(vii) The impact on patient access resulting from the cost of the prescription drug product relative to insurance benefit design;

(viii) The current or expected dollar value of drug-specific patient access programs that are supported by the manufacturer;

(ix) The relative financial impacts to health, medical, or social services costs as can be quantified and compared to baseline effects of existing therapeutic alternatives;

(x) The average patient copay or other cost-sharing for the prescription drug product in the state; and

(xi) Any other factors as determined by the board's rules and regulations.

(3) If the board is unable to determine whether a prescription drug product will produce or has produced challenges to the affordability of the drug for the state health care system, using the factors listed in subsection (2) of this subsection, the board may consider the following factors:

(i) The manufacturer's research and development costs, as indicated on the manufacturer's federal tax filing or information filed with the Federal Securities and Exchange Commission for the most recent tax year in proportion to the manufacturer's sales in the state;

(ii) The portion of direct-to-consumer marketing costs eligible for favorable federal tax treatment in the most recent tax year that are specific to the prescription drug product under review and that are multiplied by the ratio of total manufacturer in-state sales to total manufacturer sales in the United States for the product under review;

(iii) Gross and net manufacturer, pharmacy benefits manager, and wholesale distributor revenues for the prescription drug product under review for the most recent tax year;

(iv) Any additional factors proposed by the manufacturer and appropriate health insurance carriers, health maintenance organizations, managed care organizations, wholesale distributors, and pharmacy benefits managers that the board considers relevant; and

(v) Any additional factors as established by the board in its rules and regulations.

(c) On or before December 31, 2021, and each December 31 thereafter, the board shall submit to the senate finance committee and the house health, education and welfare committee, a report that includes:

(1) Price trends for prescription drug products;

(2) The number of prescription drug products that were subject to board review and the results of the review; and

(3) Any recommendations the board may have on further legislation needed to make prescription drug products more affordable in the state.

21-38-10. Trade secrets -- Confidential and propriety information.

(a) All information and data obtained by the board under this chapter that is not otherwise publicly available:

(1) Is considered to be a trade secret and confidential and proprietary information; and

(2) Is not subject to disclosure under the access to public records in chapter 2 of title 38.

(b) Only board members and staff may access trade secrets and confidential and proprietary data and information obtained under this chapter that is not otherwise publicly available.

(c) The provisions of chapter 41 of title 6, the "uniform trade secrets act", shall apply to any trade secrets and confidential and proprietary data and information obtained under this chapter that is not otherwise publicly available.

21-38-11. Enforcement.

The office of the attorney general may pursue any available remedy under state law when enforcing this chapter.

21-38-12. Setting upper payment limits for prescription drug products.

(a) If, under § 21-38-7 the board finds that it is in the best interest of the state to establish a process for setting upper payment limits for prescription drug products that it determines have led or will lead to an affordability challenge, the board, in conjunction with the stakeholder council, shall draft a plan of action for implementing the process that includes the criteria the board shall use to set upper payment limits.

(b) The criteria for setting upper payment limits shall include consideration of:

(1) The cost of administering the prescription drug product;

(2) The cost of delivering the prescription drug product to consumers; and

(3) Other relevant administrative costs related to the prescription drug product.

(c) The process for setting upper payment limits shall:

(1) Prohibit the application of an upper payment limit for a prescription drug product that is on the federal Food and Drug Administration prescription drug shortage list; and

(2) Require the board to:

(i) Monitor the availability of any prescription drug product for which it sets an upper payment limit; and

(ii) If there becomes a shortage of the prescription drug product in the state, reconsider or suspend the upper payment limit.

(d)(1) If a plan of action is drafted under subsection (a) of this section, the board shall submit the plan of action to the governor and the attorney general for approval. They shall have forty-five (45) days to approve the plan of action.

(2) The board may not set upper payment limits unless the plan is approved, in accordance with this subsection, by the governor and the attorney general.

21-38-13. Appeal of board decision.

(a) A person aggrieved by a decision of the board may request an appeal of the decision within thirty (30) days after the finding of the board.

(b) The board shall hear the appeal and make a final decision within sixty (60) days after the appeal is requested.

(c) Any person aggrieved by a final decision of the board may petition for judicial review as provided by chapter 35 of title 42 the "administrative procedure act".

21-38-14. Report -- Contents.

On or before December 1, 2024, the board, in consultation with the stakeholder council, shall report to the senate finance committee and the house health, education and welfare committee on:

(1) The legality, obstacles, and benefits of setting upper payment limits on all purchases and payor reimbursements of prescription drug products in the state; and

(2) Recommendations regarding whether the general assembly should pass legislation to expand the authority of the board to set upper payment limits to all purchases and payor reimbursements of prescription drug products in the state.

21-38-15. 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, 2021.

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EXPLANATION

BY THE LEGISLATIVE COUNCIL

OF

A N A C T

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

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This act would create a prescription drug affordability board composed of representatives of affected stakeholders designated to investigate and comprehensively evaluate drug prices for Rhode Islanders and possible ways to reduce them to make them more affordable.

This act would take effect on January 1, 2021.

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