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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. 2024

A N A C T

RELATING TO BUSINESSES AND PROFESSIONS -- RHODE ISLAND DRUG COST REVIEW COMMISSION

Introduced By: Representatives Corvese, Azzinaro, O'Brien, DeSimone, Cardillo, Craven, Kennedy, and Noret
Date Introduced: May 01, 2024

Referred To: House Health & Human Services

It is enacted by the General Assembly as follows:

SECTION 1. Legislative findings.

The general assembly hereby finds as follows:

(1) Prescription medications are as important to the health and safety of state residents as traditional public services or utilities such as transportation, gas, electric, telecommunications, and water;

(2) Rhode Island has traditionally regulated the consumer price of utilities because of the monopoly structure of the market;

(3) The cost of many prescription drugs has become increasingly unaffordable for Rhode Island residents, employers, and local governments because parts of the prescription drug market are monopolies or oligopolies, and the costs to consumers in these parts of the market are not managed;

(4) Canada has a national drug price review board that seldom has to exert its express authority in order for the industry to offer drugs to market at prices that are, on average, thirty percent (30%) less than U.S. list prices;

(5) The difference between the affordability of traditional utilities and the costs/affordability of prescription drugs is due in part to the active role of our state government in directing how much consumers pay for utilities and the corresponding inactive role of our state government in directing how much consumers pay for drugs; and

(6) State and federal agencies have a long history of health care rate setting, including for brand pharmaceuticals and biologics, and generic drugs to control health care costs.

SECTION 2. Title 5 of the General Laws entitled "BUSINESSES AND PROFESSIONS" is hereby amended by adding thereto the following chapter:

CHAPTER 19.3

RHODE ISLAND DRUG COST REVIEW COMMISSION

5-19.3-1. Definitions.

As used in this chapter:

(1) "Advisory board" or "board" means the advisory board to the DCR commission established by this chapter.

(2) "Commission" or "DCR commission" means the Rhode Island drug cost review commission established by this chapter.

(3) "Excess costs" means:

(i) Costs of appropriate utilization of a prescription drug product that exceed the therapeutic benefit relative to other therapeutic options/alternative treatments; or

(ii) Costs of appropriate utilization of a prescription drug product that are not sustainable to public and private health care systems over a ten (10) year timeframe.

(4) "WAC" means working acquisition costs.

5-19.3-2. Rhode Island drug cost review commission and advisory board established.

(a) There is hereby created and established the Rhode Island drug cost review commission (the "DCR commission"). The commission shall employ a full-time staff to receive and review statutorily-required information submissions from the makers of brand name and generic prescription drug products, the price for which triggers reporting. The commission shall be supported by a stakeholder advisory board which is also established in this chapter.

(b)(1) The commission shall have five (5) members appointed as follows: Three (3) members appointed by the governor, one member appointed by the president of the senate, and one member appointed by speaker of the house of representatives.

(2) Initial appointees appointed by the governor shall serve staggered terms of three (3), four (4), and five (5) years. All subsequent appointees shall serve five (5) year terms. The governor shall name the chair, and the commission shall elect a vice chair from its membership.

(3) Commissioners shall have expertise in health care economics or clinical medicine.

(c)(1) There is hereby established an advisory board to the commission (the "advisory board") as follows. The governor shall appoint a thirteen (13) member advisory board to advise the commission on drug cost issues.

(2) The membership of the advisory board shall consist of the following:

(i) Two (2) members representing patients and healthcare consumers;

(ii) Two (2) members representing physicians and providers;

(iii) Two (2) members representing commercial insurers;

(iv) One representing the pharmaceutical manufactures;

(v) One representative from the executive office of health and human services or the state's Medicaid program;

(vi) One representative from the office of management and budget;

(vii) Two (2) representatives from the senate, member and/or staff; and

(viii) Two (2) representatives from the house of representatives, member and/or staff.

(3) The advisory board shall elect a chair and vice chair from within its membership.

(4) One-half (1/2) of the initial appointees, as determined by the governor, shall serve staggered terms of one year, while the other half of the initial appointees shall serve an initial term of two (2) years. Subsequent appointees shall serve two (2) year terms.

(d) Members of the commission and advisory board shall adhere to the regulations set forth by the Rhode Island ethics commission.

5-19.3-3. Organization and hiring.

(a)(1) The commission shall be empowered to hire the following staff:

(i) Executive director, who shall be empowered to hire the necessary staff to assist the commission;

(ii) General legal counsel; and

(iii) Staff positions.

(2) Salaries paid to all positions shall, to the extent feasible, comport with state personnel rules and requirements. Exceptions may be made for necessary positions that have no equivalent to state government schedules in terms of expertise or function.

(b) Commissioners and board members shall be paid a per diem and travel reimbursement consistent with the state administrative procedures act.

5-19.3-4. Operations of the commission.

(a)(1) The DCR commission shall meet in public session at least every six (6) weeks to review prescription drug (biologic and pharmaceutical) product information submissions. Meetings may be cancelled or postponed upon the decision of the chair if there are no pending submissions.

(2) Each public meeting shall be scheduled in accordance with chapter 46 of title 42 ("open meetings").

(3) The commission shall publicly deliberate on whether to subject a prescription drug

product to a full cost review.

(4) The commission shall publicly review a prescription drug product cost analysis and take a public vote on whether to impose a cost or payment limit on payors for a prescription drug product.

(5) The commission may meet in executive session, as long as all decisions are made in public.

(b) Public access to data. All submissions to the commission pertaining to a drug price notices and drug cost review are to be made publicly available with the exception of information determined to be proprietary for the different industries that may be submitting information. After public notice and comment, the commission shall establish parameters for what is considered proprietary, and shall give particular attention to any pre-market submissions.

(c) The commission shall make binding decisions in the presence of a simple majority of commissioners.

5-19.3-5. Required manufacturer notice of introductory price and price increases.

(a)(1) A manufacturer shall notify the DCR commission if it is increasing the wholesale acquisition cost (WAC) of a patent-protected brand-name drug by more than ten percent (10%) or by more than ten thousand dollars ($10,000) during any twelve (12) month period (the "first threshold"), or if it intends to introduce to market a brand-name drug that has a WAC of thirty thousand dollars ($30,000) per year or per course of treatment (the "second threshold"). The notice shall be provided in writing at least thirty (30) days prior to the planned effective date of the increase or launch and include a justification as detailed in this section.

(2) After consultation with stakeholders and experts, the commission shall establish a third threshold that, when breached, triggers manufacturer reporting for brand prescription drugs, including biologics and biosimilars. The third, distinct threshold shall achieve reporting by branded products that have launch prices or price increases below the first and second thresholds identified in subsection (a)(1) of this section, but impose costs on the state health care system that create significant challenges to affordability.

(b)(1) A manufacturer shall notify the DCR commission if it is increasing the WAC of a generic or off-patent sole source branded product drug by more than twenty-five percent (25%) or by more than three hundred dollars ($300) during any twelve through twenty (12-20) month period (the "first threshold"), or if it intends to introduce to market a generic drug that has a WAC of three thousand dollars ($3,000) or more annually (the "second threshold"). The notice shall be provided in writing at least thirty (30) days prior to the planned effective date of the increase or launch and include a justification as detailed in this section.

(2) After consultation with stakeholders and experts, the commission shall establish a third threshold that when breached, triggers manufacturer reporting for generic and off-patent, sole source branded prescription drugs. The third, distinct threshold shall achieve reporting by products that have price increases below the thresholds in subsection (b)(1) of this section, but impose costs on the state health care system that create significant challenges to affordability.

(c) Justification for the proposed launch price or price increases specified in subsections (a) and (b) of this section shall include all documents and research related to the manufacturer's selection of the launch price or price increase, including, but not limited to, life cycle management, net average price in the state (the net of all price concessions but excluding in-kind concessions), market competition and context, projected revenue, and if available, estimated value/cost-effectiveness of the product.

5-19.3-6. Criteria for selection of drugs for review of cost.

(a) The DCR commission will keep the public informed about manufacturer price decision reporting. The commission shall provide the public an opportunity to request commission review of the cost of any prescription drug that triggered reporting under this chapter.

(b) The commission chair shall review the public comments and decide whether to undertake a review of a particular drug that triggered reporting under this chapter. The chair can decide that the commission shall undertake a review in the absence of public comments.

(c) The commission members can request a vote on whether or not to undertake a review if there is not consensus with the decision of the chair.

5-19.3-7. Determining excess costs to payors and consumers.

(a) Once a decision has been made to undertake a cost review pursuant to this chapter, the DCR commission review shall determine if appropriate utilization (utilization fully consistent with the FDA label) of a prescription drug product has lead or shall lead to excess costs for health care systems in the state.

(b) Factors the commission may consider in determining cost and excess cost include the following:

(1) The price at which the prescription drug has been/will be sold in the state;

(2) The average monetary price concession/discount/rebate the manufacturer provides to payors in the state/or is expected to provide to payors in the state as reported by manufacturers and health plans;

(3) The price at which therapeutic alternates have been/shall be sold in the state;

(4) The average monetary price concession/discount/rebate the manufacturer provides to health plan payors in the state or is expected to provide to payors in the state for therapeutic

alternates;

(5) The relative clinical merits of the product under review compared to therapeutic alternates;

(6) The cost to payors based on patient access consistent with FDA labeled indication(s);

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

(8) The current or expected value of manufacturer-supported, drug-specific, patient access programs;

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

(10) Other such factors as may be specified in regulation by the commission.

(c) If, after considering the factors in subsection (b) of this section, the commission is unable to determine if a prescription drug product shall produce or has produced excess costs, then the commission may consider the following:

(1) Manufacturer research and development costs, as shown on the company's federal tax filing for the most recent tax year multiplied by the proportion of manufacturer in-state sales to United States sales;

(2) That portion of direct to consumer marketing costs eligible for favorable federal tax treatment in the most recent tax year, which 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 United States sales for the product under review;

(3) Gross and net manufacturer revenues for the most recent tax year; and

(4) Any additional factors which can be specified in regulations or that the commission considers relevant to the circumstances, as may be proposed by the manufacturer.

5-19.3-8. Commission determinations, compliance, and remedies.

(a) In the event the commission finds that the spending on the prescription drug product under review creates excess costs for payors and consumers, the commission shall establish the level of reimbursement that shall be billed and paid among payors and pharmacies/administering providers, wholesalers/distributors and pharmacies/administering providers, and pharmacies/administering providers and uninsured consumers or consumers in a deductible period.

(b) Instances of failure to bill and pay at commission-established levels under this chapter shall be referred to the office of the attorney general.

(1) Upon a finding of non-compliance with the commission requirements, the attorney general may pursue remedies consistent with the provisions of the general laws, including, but not

limited to, the provisions of this chapter, and of chapter 31 of title 21 ("Rhode Island food, drugs, and cosmetics act"), of chapter 13 of title 6 ("unfair sales practices"), of chapter 13.1 of title 6 ("deceptive trade practices"), or in the case of intentional profiteering, other appropriate criminal statutes.

(2) It shall not be considered non-compliance if a health care stakeholder obtains price concessions from a manufacturer that result in an insurer's net cost lower than the rate established by the commission.

(3) The attorney general shall provide guidance to stakeholders concerning activities that could be considered non-compliant, in addition to payment transactions where drug costs exceed the commission established limit.

(c) Instances of manufacturer failure to report as required under the provisions of this chapter shall be referred to the attorney general for review regarding violations of consumer protection laws.

5-19.3-9. Appeals.

Individuals and entities affected by a decision of the DCR commission can request an appeal within thirty (30) days of issuance of the commission decision. The full commission shall hear the appeal and make a decision within sixty (60) days of the filing of the appeal. A decision from the full commission shall be considered a final administrative decision and remedy, and shall be subject to review pursuant to the administrative procedures act and more specifically as set forth in § 42-35-15.

5-19.3-10. Financing.

(a) The DCR commission chair shall recommend to the general assembly financing options within six (6) months of establishment of the DCR commission.

(b) The commission shall be funded for the first two (2) years with such sums as are necessary but not to exceed five hundred thousand dollars ($500,000) per year.

5-19.3-11. Annual reporting.

The DCR commission shall report annually to the public on general drug price trends, the number of companies required to report because of drug pricing decisions, and the number of products that were subject to commission review and analysis, including the results of that analysis, as well as the number and disposition of appeals and judicial reviews.

SECTION 3. This act shall take effect upon passage.

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EXPLANATION

BY THE LEGISLATIVE COUNCIL

OF

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RELATING TO BUSINESSES AND PROFESSIONS -- RHODE ISLAND DRUG COST REVIEW COMMISSION

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This act would create the Rhode Island drug cost review commission and direct that the commission review certain submissions from drug manufacturers/sellers that concern drug costs, and make determinations as to whether the cost of a drug under review is affordable. The commission would be authorized to establish an affordable cost or payment rate for the drugs upon many stakeholders. The act would also establish an advisory board to assist the commission and violations would be enforced by the attorney general.

This act would take effect upon passage.

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