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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. 2022

A N A C T

RELATING TO BUSINESSES AND PROFESSIONS -- THE DRUG COST TRANSPARENCY ACT

Introduced By: Representatives Ackerman, McNamara, Kazarian, McGaw, Bennett, Filippi, Cassar, and Kennedy
Date Introduced: January 28, 2022

Referred To: House Health & Human Services

It is enacted by the General Assembly as follows:

SECTION 1. Title 5 of the General Laws entitled "BUSINESSES AND PROFESSIONS" is hereby amended by adding thereto the following chapter:

CHAPTER 19.3

THE DRUG COST TRANSPARENCY ACT

5-19.3-1. Short title.

This chapter shall be known and may be cited as "The Drug Cost Transparency Act."

5-19.3-2. Definitions.

(1) "Animal health product" means a medical product approved and licensed for use in animal or veterinary medicine, including a pharmaceutical, a biologic, an insecticide, and a parasiticide.

(2) "Department" means the department of business regulation.

(3) "Director" means the director of the department of business regulation, or designee.

(4) "Health benefit plan" means an individual, blanket, or group plan, policy, or contract for health care services issued or delivered by a health benefit plan issuer in this state.

(5) "Health benefit plan issuer" means an insurance company, a health maintenance organization, or a hospital and medical service corporation.

(6) "Manufacturer" or "pharmaceutical drug manufacturer" means a pharmaceutical, biological product, or medical device manufacturer or any other person who is engaged in the

production, preparation, propagation, compounding, processing, marketing, packaging, repacking, distributing, or labeling of prescribed products. The term does not include a wholesale distributor of biological products, a retailer, or a pharmacist. The term also does not include a manufacturer whose only prescribed products are classified as Class I by the U.S. Food and Drug Administration, are exempt from pre-market notification under § 510(k) of the Federal Food, Drug and Cosmetic Act 21 U.S.C. 360, and are sold over the counter without a prescription.

(7) "Pharmacy benefit manager" means a person or entity who contracts with a pharmacy on behalf of an insurer, health plan, or third-party administrator to administer to manage prescription drug benefits.

(8) "Prescription drug" means a drug as defined in 21 U.S.C. § 321.

(9) "Rebate" means a discount or concession that affects the price of a prescription drug to a pharmacy benefit manager or health benefit plan issuer for a prescription drug manufactured by the pharmaceutical drug manufacturer.

(10) "Specialty drug" means a prescription drug covered under Medicare Part D that exceeds the specialty tier cost threshold established by the Centers for Medicare and Medicaid Services.

(11) "Utilization management" means a set of formal techniques designed to monitor the use of, or evaluate the medical necessity, appropriateness, efficacy, or efficiency of, health care services, procedures, or settings.

5-19.3-3. Drug pricing disclosure.

(a) Not later than the fifteenth day of each calendar year, a pharmaceutical drug manufacturer shall submit a report to the director stating the current wholesale acquisition cost information for the U.S. Food and Drug Administration-approved drugs sold in or into this state by that manufacturer.

(b) The director shall develop an Internet website to provide to the general public drug price information submitted under subsection (a) of this section. The Internet website shall be made available on the department's website with a dedicated link that is prominently displayed on the home page or by a separate easily identifiable Internet address.

(c) This section applies only to a drug with a wholesale acquisition cost of at least one hundred dollars ($100) for a thirty (30) day supply before the effective date of an increase described by this section. Not later than thirty (30) days after the effective date of an increase of forty percent (40%) or more over the preceding three (3) calendar years or fifteen percent (15%) or more in the preceding calendar year in the wholesale acquisition cost of a drug to which this section applies, a pharmaceutical drug manufacturer shall submit a report to the director. The report shall include the

following information:

(1) The name of the drug;

(2) Whether the drug is a brand name or generic;

(3) The effective date of the change in wholesale acquisition cost;

(4) Aggregate, company-level research and development costs for the most recent year for which final audit data is available;

(5) The name of each of the manufacturer's prescription drugs approved by the U.S. Food and Drug Administration in the previous three (3) calendar years;

(6) The name of each of the manufacturer's prescription drugs that lost patent exclusivity in the United States in the previous three (3) calendar years; and

(7) A statement regarding the factor or factors that caused the increase in the wholesale acquisition costs and an explanation of the role of each factor's impact on the cost.

(d) The quality and types of information and data that a pharmaceutical drug manufacturer submits to the director under subsection (c) of this section shall be consistent with the quality and types of information and data that the manufacturer includes in the manufacturer's annual consolidated report on Securities and Exchange Commission Form 10-K or any other public disclosure.

(e) Not later than sixty (60) days after receipt of the report submitted under subsection (c) of this section, the director shall publish the report on the Internet website described by subsection (b) of this section.

5-19.3-4. Pharmacy benefit manager information.

(a) Not later than February 1 of each year, each pharmacy benefit manager shall file a report with the director. The report shall state for the immediately preceding calendar year:

(1) The aggregated rebates, fees, price protection payments, and any other payments collected from pharmaceutical drug manufacturers; and

(2) The aggregated dollar amount of rebates, fees, price protection payments, and any other payments collected from pharmaceutical drug manufactures that were:

(i) Passed to:

(A) Health benefit plan issuers; or

(B) Enrollees at the point of sale of a prescription drug; or

(ii) Retained as revenue by the pharmacy benefit manager.

(b) Notwithstanding subsection (a) of this section, the report due not later than February 1, 2023, under subsection (a) of this section, shall state the required information for the immediately preceding three (3) calendar years in addition to stating the required information for the preceding

calendar year. The requirement for information of the preceding three (3) years shall only apply to the report due not later than February 1, 2023.

(c) A report submitted by a pharmacy benefit manager shall not disclose the identity of a specific health benefit plan or enrollee, the price charged for a specific prescription drug or class of prescription drugs, or the amount of any rebate or fee provided for a specific prescription drug or class of prescription drugs.

(d) Not later than May 1 of each year, the director shall publish the aggregated data from all reports for that year required by this section in an appropriate location on the department's Internet website. The combined aggregated data from the reports shall be published in a manner that does not disclose or tend to disclose proprietary or confidential information of any pharmacy benefit manager.

5-19.3-5. Health benefit plan issuer information.

(a) Not later than February 1 of each year, each health benefit plan issuer shall submit to the director a report that states for the immediately preceding calendar year:

(1) The names of the twenty-five (25) most frequently prescribed prescription drugs across all plans;

(2) The percent increase in annual net spending for prescription drugs across all plans;

(3) The percent increase in premiums that were attributable to prescription drugs across all plans;

(4) The percentage of specialty drugs with utilization management requirements across all plans; and

(5) The premium reductions that were attributable to specialty drug utilization management.

(b) A report submitted by a health benefit plan issuer shall not disclose the identity of a specific health benefit plan or the price charged for a specific prescription drug or class of prescription drugs.

(c) Not later than May 1 of each year, the director shall publish the aggregated data from all reports for that year required by this section in an appropriate location on the department's Internet website. The combined aggregated data from the reports shall be published in a manner that does not disclose or tend to disclose proprietary or confidential information of any health benefit plan issuer.

5-19.3-6. Rules and regulations.

The director shall adopt rules and regulations to implement the provisions of this chapter.

5-19.3-7. Administrative penalty.

The director may assess an administrative penalty up to one thousand dollars ($1,000) per violation by any person or entity that fails to comply with any provision of this chapter or any rule or regulation issued by the director pursuant to § 5-19.3-6.

5-19.3-8. Appeal procedure.

Any administrative penalty assessed by the director pursuant to § 5-19.3-7 may be appealed in accordance with the chapter 35 of title 42 ("the administrative procedures act").

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 BUSINESSES AND PROFESSIONS -- THE DRUG COST TRANSPARENCY ACT

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This act would allow drug cost transparency by requiring reports be submitted by drug manufacturers, pharmacy benefit managers and health benefit plan insurers for analysis to the director of the department of business regulation regarding prescription drugs.

This act would take effect upon passage.

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