2020 -- S 2318

========
LC003958
========

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 - DRUG COST TRANSPARENCY ACT

Introduced By: Senators Ruggerio, Goodwin, McCaffrey, Miller, and Coyne

Date Introduced: February 05, 2020

Referred To: Senate 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

DRUG COST TRANSPARENCY ACT

21-38-1. Short title.

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

21-38-2. Definitions.

As used in this chapter:

(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) "Director" means the director of the Rhode Island department of health.

(3) "Department" means the Rhode Island department of health.

(4) "Pharmaceutical drug manufacturer" means a person engaged in the business of producing, preparing, propagating, compounding, converting, processing, packaging, repackaging, labeling, or distributing a drug. The term "pharmaceutical drug manufacturer" does not include a wholesale distributor or retailer of prescription drugs or a pharmacist licensed under chapter 19.1 of title 5.

(5) "Prescription drug" and "drug" means a drug as defined in 21 U.S.C. § 321, except

that the term "prescription drug" or "drug" does not include a device or an animal health product.

(6) "Wholesale acquisition cost" means, with respect to a drug, the pharmaceutical drug manufacturer's list price for the drug charged to wholesalers or direct purchasers in the United States, as reported in wholesale price guides or other publications of drug pricing data. The cost does not include any rebates, prompt pay or other discounts, or other reductions in price.

21-38-3. Disclosure of drug pricing information.

(a) On or before February 1, 2021 and every February 1 of each year thereafter, a pharmaceutical drug manufacturer shall submit a report to the director stating the current wholesale acquisition cost information for the United States Food and Drug Administration-approved drugs sold in or offered for sale in 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 of health's Internet website with a dedicated link that is prominently displayed on the home page or by a separate easily identifiable Internet address.

(c) This subsection 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 subsection. Not later than the thirtieth day 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 subsection applies, a pharmaceutical drug manufacturer shall submit a report to the director. The report must include the following information:

(1) The name of the drug;

(2) Whether the drug is a brand name or a 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 United States 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 cost 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 must 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 the sixtieth day after receipt of the report submitted under subsection (c) of this section, the director shall publish the report on the department of health's Internet website described by subsection (b) of this section.

(f) The director shall promulgate any and all rules and regulations deemed necessary for the implementation of this chapter.

SECTION 2. Chapter 27-18 of the General Laws entitled "Accident and Sickness Insurance Policies" is hereby amended by adding thereto the following section:

27-18-85. Drug cost transparency.

(a) The following definitions as used in this section shall apply:

(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) "Commissioner" or "health insurance commissioner" means that individual appointed pursuant to § 42-14.5-1.

(3) "Health benefit plan" has the same meaning as § 27-18-1.1.

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

(5) "Pharmaceutical drug manufacturer" means a person engaged in the business of producing, preparing, propagating, compounding, converting, processing, packaging, repackaging, labeling, or distributing a drug. The term "pharmaceutical drug manufacturer" does not include a wholesale distributor or retailer of prescription drugs or a pharmacist licensed under chapter 19.1 of title 5.

(6) "Pharmacy benefit manager" means an entity doing business in this state that contracts to administer or manage prescription-drug benefits on behalf of any carrier that provides prescription-drug benefits to residents of this state.

(7) "Prescription drug" and "drug" means a drug as defined in 21 U.S.C. § 321, except that the term "prescription drug" or "drug" does not include a device or an animal health product.

(8) "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.

(9) "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.

(10) "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.

(b) On or before February 1, 2021 and every February 1 of each year thereafter, each pharmacy benefit manager shall file a report with the commissioner. The report must 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 manufacturers that were:

(i) Passed to:

(A) A health benefit plan issuer; or

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

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

(c) Notwithstanding subsection (b) of this section, the report due after February 1, 2021, under that subsection must state the required information for the immediately preceding three (3) calendar years in addition to stating the required information for the preceding calendar year. This subsection (c) of this section shall not apply to any report required after February 1, 2021.

(d) A report submitted by a pharmacy benefit manager may 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.

(e) On or before February 1, 2021 and every February 1 of each year thereafter, each health benefit plan issuer shall submit to the commissioner 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.

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

(g) On or before May 1 of each year, the commissioner shall collaborate with the Rhode Island department of health to publish the aggregated data from all reports for that year required by this section in an appropriate location on an Internet website created pursuant to § 21-38-3(b). The combined aggregated data from the reports must be published in a manner that does not disclose or tend to disclose proprietary or confidential information of any pharmacy benefit manager or health benefit plan issuer.

(h) The commissioner shall promulgate any and all rules and regulations deemed necessary for the implementation of this section.

SECTION 3. Chapter 27-19 of the General Laws entitled "Nonprofit Hospital Service Corporations" is hereby amended by adding thereto the following section:

27-19-77. Drug cost transparency.

(a) The following definitions as used in this section shall apply:

(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) "Commissioner" or "health insurance commissioner" means that individual appointed pursuant to § 42-14.5-1.

(3) "Health benefit plan" has the same meaning as § 27-18-1.1.

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

(5) "Pharmaceutical drug manufacturer" means a person engaged in the business of producing, preparing, propagating, compounding, converting, processing, packaging, repackaging, labeling, or distributing a drug. The term "pharmaceutical drug manufacturer" does not include a wholesale distributor or retailer of prescription drugs or a pharmacist licensed under chapter 19.1 of title 5.

(6) "Pharmacy benefit manager" means an entity doing business in this state that contracts to administer or manage prescription-drug benefits on behalf of any carrier that provides prescription-drug benefits to residents of this state.

(7) "Prescription drug" and "drug" means a drug as defined in 21 U.S.C. § 321, except

that the term "prescription drug" or "drug" does not include a device or an animal health product.

(8) "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.

(9) "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.

(10) "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.

(b) On or before February 1, 2021 and every February 1 of each year thereafter, each pharmacy benefit manager shall file a report with the commissioner. The report must 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 manufacturers that were:

(i) Passed to:

(A) A health benefit plan issuer; or

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

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

(c) Notwithstanding subsection (b) of this section, the report due on or before February 1, 2021, under that subsection must state the required information for the immediately preceding three (3) calendar years in addition to stating the required information for the preceding calendar year. This subsection (c) of this section shall not apply to any report required after February 1, 2021.

(d) A report submitted by a pharmacy benefit manager may 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.

(e) On or before February 1, 2021 and every February 1 of each year thereafter, each health benefit plan issuer shall submit to the commissioner 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.

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

(g) On or before May 1 of each year, the commissioner shall collaborate with the Rhode Island department of health to publish the aggregated data from all reports for that year required by this section in an appropriate location on an Internet website created pursuant to § 21-38-3(b). The combined aggregated data from the reports must be published in a manner that does not disclose or tend to disclose proprietary or confidential information of any pharmacy benefit manager or health benefit plan issuer.

(h) The commissioner shall promulgate any and all rules and regulations deemed necessary for the implementation of this section.

SECTION 4. Chapter 27-20 of the General Laws entitled "Nonprofit Medical Service Corporations" is hereby amended by adding thereto the following section:

27-20-72. Drug cost transparency.

(a) The following definitions as used in this section shall apply:

(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) "Commissioner" or "health insurance commissioner" means that individual appointed pursuant to § 42-14.5-1.

(3) "Health benefit plan" has the same meaning as § 27-18-1.1.

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

(5) "Pharmaceutical drug manufacturer" means a person engaged in the business of producing, preparing, propagating, compounding, converting, processing, packaging, repackaging, labeling, or distributing a drug. The term "pharmaceutical drug manufacturer" does

not include a wholesale distributor or retailer of prescription drugs or a pharmacist licensed under chapter 19.1 of title 5.

(6) "Pharmacy benefit manager" means an entity doing business in this state that contracts to administer or manage prescription-drug benefits on behalf of any carrier that provides prescription-drug benefits to residents of this state.

(7) "Prescription drug" and "drug" means a drug as defined in 21 U.S.C. § 321, except that the term "prescription drug" or "drug" does not include a device or an animal health product.

(8) "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.

(9) "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.

(10) "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.

(b) On or before February 1, 2021 and every February 1 of each year thereafter, each pharmacy benefit manager shall file a report with the commissioner. The report must 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 manufacturers that were:

(i) Passed to:

(A) A health benefit plan issuer; or

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

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

(c) Notwithstanding subsection (b) of this section, the report due on or before February 1, 2021, under that subsection must state the required information for the immediately preceding three (3) calendar years in addition to stating the required information for the preceding calendar year. This subsection (c) of this section shall not apply to any report required after February 1, 2021.

(d) A report submitted by a pharmacy benefit manager may 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.

(e) On or before February 1, 2021 and every February 1 of each year thereafter, each health benefit plan issuer shall submit to the commissioner 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.

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

(g) On or before May 1 of each year, the commissioner shall collaborate with the Rhode Island department of health to publish the aggregated data from all reports for that year required by this section in an appropriate location on an Internet website created pursuant to § 21-38-3(b). The combined aggregated data from the reports must be published in a manner that does not disclose or tend to disclose proprietary or confidential information of any pharmacy benefit manager or health benefit plan issuer.

(h) The commissioner shall promulgate any and all rules and regulations deemed necessary for the implementation of this section.

SECTION 5. Chapter 27-41 of the General Laws entitled "Health Maintenance Organizations" is hereby amended by adding thereto the following section:

27-41-90. Drug cost transparency.

(a) The following definitions as used in this section shall apply:

(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) "Commissioner" or "health insurance commissioner" means that individual appointed pursuant to § 42-14.5-1.

(3) "Health benefit plan" has the same meaning as § 27-18-1.1.

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

(5) "Pharmaceutical drug manufacturer" means a person engaged in the business of producing, preparing, propagating, compounding, converting, processing, packaging, repackaging, labeling, or distributing a drug. The term "pharmaceutical drug manufacturer" does not include a wholesale distributor or retailer of prescription drugs or a pharmacist licensed under chapter 19.1 of title 5.

(6) "Pharmacy benefit manager" means an entity doing business in this state that contracts to administer or manage prescription-drug benefits on behalf of any carrier that provides prescription-drug benefits to residents of this state.

(7) "Prescription drug" and "drug" means a drug as defined in 21 U.S.C. § 321, except that the term "prescription drug" or "drug" does not include a device or an animal health product.

(8) "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.

(9) "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.

(10) "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.

(b) On or before February 1, 2021 and every February 1 of each year thereafter, each pharmacy benefit manager shall file a report with the commissioner. The report must 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 manufacturers that were:

(i) Passed to:

(A) A health benefit plan issuer; or

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

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

(c) Notwithstanding subsection (b) of this section, the report due on or before February 1,

2021, under that subsection must state the required information for the immediately preceding three (3) calendar years in addition to stating the required information for the preceding calendar year. This subsection (c) of this section shall not apply to any report required after February 1, 2021.

(d) A report submitted by a pharmacy benefit manager may 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.

(e) On or before February 1, 2021 and every February 1 of each year thereafter, each health benefit plan issuer shall submit to the commissioner 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.

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

(g) On or before May 1 of each year, the commissioner shall collaborate with the Rhode Island department of health to publish the aggregated data from all reports for that year required by this section in an appropriate location on an Internet website created pursuant to § 21-38-3(b). The combined aggregated data from the reports must be published in a manner that does not disclose or tend to disclose proprietary or confidential information of any pharmacy benefit manager or health benefit plan issuer.

(h) The commissioner shall promulgate any and all rules and regulations deemed necessary for the implementation of this section.

SECTION 6. This act shall take effect upon passage.

========
LC003958
========

EXPLANATION

BY THE LEGISLATIVE COUNCIL

OF

A N A C T

RELATING TO FOOD AND DRUGS - DRUG COST TRANSPARENCY ACT

***

This act would require pharmaceutical drug manufacturers to provide wholesale drug acquisition cost information to the department of health (DOH) and pharmacy benefit managers to provide information relating to drug prices, rebates, fees and drug sales to the health insurance commissioner on a yearly basis on or before February 1, 2021 and thereafter.

This act would take effect upon passage.

========
LC003958
========