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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. 2018

A N A C T

RELATING TO BUSINESSES AND PROFESSIONS - PRESCRIPTION DRUG SALES - REPRESENTATIVE DISCLOSURE ACT

Introduced By: Representatives Edwards, Kennedy, Newberry, Canario, and Shekarchi

Date Introduced: February 28, 2018

Referred To: House Health, Education & Welfare

It is enacted by the General Assembly as follows:

SECTION 1. Legislative findings and declaration of purpose. The general assembly hereby finds and declares that:

(1) Containing health care costs requires containing prescription drug costs. The costs of prescription drugs have been increasing dramatically. In order to contain prescription drug costs, it is essential to understand the drivers of those costs, including increases in prescriptions and changes in prescription patterns from low-cost to high-cost drugs.

(2) Drug companies employ pharmaceutical sales representatives to increase sales by persuading providers of health care to prescribe certain drugs. Sales representatives may provide education to the provider of health care, but often also include inducements in the form of gifts and drug samples.

(3) Drug sales representatives often have access to physician prescription tracking data.

(4) The state has an interest in requiring disclosures and regulating the practice of drug sales representatives.

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

CHAPTER 19.3

THE PRESCRIPTION DRUG SALES REPRESENTATIVE DISCLOSURE ACT

5-19.3-1. Short title.

This chapter shall be known and may be cited as the "The Prescription Drug Sales Representative Disclosure Act."

5-19.3-2. Definitions.

As used in this chapter, the following words and terms shall have the following meaning:

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

(2) "Director" means the director of the department of business regulation or their designee.

(3) "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) (21 U.S.C. 360 § 510 (k)) of the Federal Food, Drug and Cosmetic Act, and are sold over the counter without a prescription.

(4) "Medical facility" means any freestanding emergency-care facility, health care facility, physician or podiatry ambulatory-surgery center, or other similar entity licensed by the state.

(5) "Pharmaceutical sales representative" means a person who markets prescription drugs to providers of health care licensed, certified or registered in this state, pharmacies or employees thereof, operators or employees of medical facilities or persons licensed or certified by the state.

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

(7) "Provider of health care" means any person licensed in this state to administer or prescribe a prescription drug.

5-19.3-3. Pharmaceutical manufacturer and sales representative registration, disclosure, and transparency report.

(a) A manufacturer of a prescription drug shall provide to the department a list of each pharmaceutical sales representative who markets prescription drugs on behalf of the manufacturer to providers of health care in this state, pharmacies or employees thereof, or operators or employees of medical facilities or persons licensed in this state.

(1) The manufacturer shall inform the department by any means acceptable to the department of a change in the manufacturer's list within thirty (30) days of the change. Failure to timely inform the department of a change may result in a penalty to be determined by the

department.

(2) The manufacturer shall refile or update the list annually.

(b) The department shall provide electronic access to the most recent list provided by each manufacturer pursuant to subsection (a) of this section to each provider of health care licensed, certified or registered in this state, operator of a pharmacy, and operator of a medical facility, or person licensed or certified under the provisions of title 5 for the purposes of ensuring compliance with the requirements of subsection (c) of this section. The department shall also provide electronic access to the information to the department of health and public access via the department's website. This subsection must not be construed to impose any duty on a provider of health care, operator of a pharmacy, or operator of a medical facility or person licensed or certified under the provisions of title 5 to ensure such compliance.

(c) A person who is not included on a current list submitted pursuant to subsection (a) of this section shall not market prescription drugs on behalf of a manufacturer to any provider of health care licensed, certified or registered in this state, pharmacy or employee thereof, operator or employee of a medical facility or person licensed or certified under the provisions of title 5.

(d) On or before March 1 of each year, each person who was included on a list of pharmaceutical sales representatives submitted pursuant to subsection (a) of this section at any time during the immediately preceding calendar year shall submit to the department a report, which must include, for the immediately preceding calendar year:

(1) A list of providers of health care, pharmacies and employees thereof, and operators and employees of medical facilities and persons licensed or certified under the provisions of title 5 to whom the pharmaceutical sales representative provided:

(i) Any type of compensation, gift, or thing of value, with a value that exceeds ten dollars ($10.00); or

(ii) Total compensation, gift, or thing of value, with a value that exceeds one hundred dollars ($100) in aggregate; and

(2) The name and manufacturer of each prescription drug for which the pharmaceutical sales representative provided a free sample to a provider of health care licensed, certified or registered in this state, pharmacy or employee thereof, or operator or employee of a medical facility or person licensed or certified under the provisions of title 5.

(e) The department shall analyze annually the information submitted pursuant to subsection (d) of this section and compile a report on the activities of pharmaceutical sales representatives in this state. On or before June 1 of each year, the department shall:

(i) Post the report on the website maintained by the department; and

(ii) Submit the report to the governor, the director of the department of health, the commissioner of the office of health insurance, the speaker of the house and the senate president.

5-19.3-4. Fees and penalties.

(a) A fee in the amount of fifty-five dollars ($55.00) annually shall be charged by the director from each manufacturer, per each pharmaceutical sales representative listed by the manufacturer. All revenue collected pursuant to this chapter shall be deposited as restricted receipts available to the department as described in § 42-14-9.

(b) The attorney general may bring an action in the civil division of the superior court, Providence County for injunctive relief, costs, and attorneys' fees, and to impose, on a manufacturer that fails to provide the information required by this chapter, a civil penalty of no more than ten thousand dollars ($10,000) per violation. Each unlawful failure to provide information shall constitute a separate violation. In any action brought pursuant to this section, the attorney general shall have the same authority to investigate and to obtain remedies as if the action were brought under the deceptive trade practices act, chapter 13.1 of title 6.

SECTION 3. This act shall take effect on January 1, 2019.

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EXPLANATION

BY THE LEGISLATIVE COUNCIL

OF

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RELATING TO BUSINESSES AND PROFESSIONS - PRESCRIPTION DRUG SALES - REPRESENTATIVE DISCLOSURE ACT

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This act would require prescription drug manufacturers to file a detailed, updated list of each pharmaceutical sales representative and to pay an annual fee for each name listed with the department of business regulation. Failure to comply would result in civil penalties.

This act would take effect on January 1, 2019.

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