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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. 2025

A N A C T

RELATING TO FOOD AND DRUGS -- RHODE ISLAND FOOD, DRUGS, AND COSMETICS ACT

Introduced By: Senators Lauria, Valverde, Kallman, Murray, Felag, DiMario, Pearson, Thompson, Urso, and Acosta
Date Introduced: February 26, 2025

Referred To: Senate Health & Human Services

It is enacted by the General Assembly as follows:

SECTION 1. Section 21-31-16.1 of the General Laws in Chapter 21-31 entitled "Rhode Island Food, Drugs, and Cosmetics Act" is hereby amended to read as follows:

21-31-16.1. ~~Substitution of generic drugs and biological products~~ Substitution of generic drugs, biological products, devices and supplies, and therapeutically equivalent products by a pharmacist.

(a) Drug product selection. The director shall permit substitution of less expensive generic, chemical, or brand-name drugs and pharmaceuticals, excluding biological products, considered by the director as therapeutically equivalent and interchangeable with specific, brand-name drugs and pharmaceuticals, if they are found to be in compliance with § 21-31-16 and standards set forth by the United States Food and Drug Administration under §§ 505 and 507 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 355 and 357. The director shall consider, but not be limited to, the determination of the United States Food and Drug Administration, or its successor agency, as published under §§ 505 and 507 of the Federal Food, Drug, and Cosmetic Act. ~~The director shall provide for the distribution of copies of lists of prescription drug products that the director deems, after evaluation, not to be therapeutically equivalent, and revisions to the lists, among physicians and pharmacists licensed and actively engaged in practice within the state, and other appropriate individuals, and shall supply a copy to any person on request. The list shall be revised from time to time so as to include new, pertinent information on approved prescription drug products, reflecting~~

~~current information as to standards for quality, safety, effectiveness, and therapeutic equivalence.~~

(b) The director shall provide a therapeutically equivalent product list, which is a list of products that can be substituted for another specific product. (The products on the therapeutically equivalent product list are outside of brand/generic switches or biological interchangeable products.)

(1) The therapeutically equivalent product list shall provide the prescribed products' name, dosage, directions, package size/quantity prescribed and the therapeutically equivalent product's name, dosage, directions, package size/quantity prescribed.

(2) Pharmacists utilizing the therapeutically equivalent product list shall document the change on the prescription and notify the prescribing provider of the change within seven (7) calendar days.

(3) Pharmacists shall not be mandated to utilize the therapeutically equivalent product list nor are consumers required to accept a medication switch/substitution based on the therapeutically equivalent product list.

(4) The therapeutically equivalent product list applies to initial starts or "first fills" as well as those continuing care.

(5) The list shall be reviewed and revised periodically, but not less frequently than every three (3) years to include new, pertinent information on approved prescription-drug products, reflecting current information as to standards for quality, safety, effectiveness, and therapeutic equivalence.

(6) The director shall consult representatives appointed by the Rhode Island Pharmacist's Association (RIPA), Nurse Practitioner Alliance of Rhode Island (NPARI), and Rhode Island Medical Society (RIMS) for review and or consultation of the interchange list. Each organization shall have one appointed representative by their respective president or executive leadership.

~~(b)~~(c) Appropriations. The director shall provide necessary space, personnel, and material to carry out the provisions of this section.

~~(c)~~(d) Liability. There shall be no civil liability incurred, and no cause of action of any nature shall arise, against the director, designated agents, or employees, as a result of the listing or omission of drugs or pharmaceuticals or biological products for product selection.

~~(d)~~(e) Annual reports. The director shall make annual reports to the general assembly by February 10 of each year showing a list of approved prescription-drug products with therapeutic equivalence and approved prescription interchangeable biological products, and an estimate of the average savings to the general public.

~~(e)~~(f) Pharmacists. When a pharmacist dispenses a therapeutically equivalent drug product

or interchangeable biological product, there shall be no additional liability imposed on the prescriber who authorizes that product selection, or on the pharmacist dispensing the product selection from a physician's oral or written order.

~~(f)~~(g) Enforcement provisions. It is made the duty of the department of health, its agents designated by the director of health, and of all peace officers within the state to enforce all provisions of this section and of §§ 5-19.1-19, 5-37-18 — 5-37-18.2, and 21-31-3.

~~(g)~~(h) Biological-product selection. The director shall permit substitution of a less-expensive biological product, as defined in § 5-19.1-2, for a prescribed biological product only if said less-expensive biological product is an interchangeable biological product as defined in § 5-19.1-2. The director shall maintain on the Rhode Island state department of health website, a link to the current list of each biological product determined by the United States Food and Drug Administration to be an interchangeable biological product.

(i) Device product selection. The director shall permit substitution of a less-expensive device, or supply as defined in § 5-19.1-2, for a prescribed product only if said less-expensive product is approved for the same indication, use, and if applicable, formulation. In the event that a class of devices monitor differently (i.e. single reading vs continuous), the interchanged device must monitor in the same fashion. The director shall maintain on the department of health website a link to the current list of each product to be an interchangeable device or supply. Such examples suitable for interchange include, but are not limited to, supplies and devices used to monitor glucose, administer insulin or another pharmacologic product as determined by the director.

SECTION 2. This act shall take effect on January 1, 2026.

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EXPLANATION

BY THE LEGISLATIVE COUNCIL

OF

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RELATING TO FOOD AND DRUGS -- RHODE ISLAND FOOD, DRUGS, AND COSMETICS ACT

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This act would amend the types of less expensive generic products which pharmacists may prescribe to include "devices and supplies" and "therapeutically equivalent products" and would require the director to provide a list of therapeutically equivalent products.

This act would take effect on January 1, 2026.

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