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

Drug products deemed to be therapeutically equivalent are outside of brand/generic switches or biological interchangeable products.

(1) Pharmacists substituting therapeutically equivalent products shall document the change on the prescription and notify the prescribing provider of the change within seven (7) calendar days.

(2) Pharmacists shall not be mandated to substitute therapeutically equivalent products nor are patients required to accept a medication substitution.

(3) Therapeutic interchange applies to initial starts or "first fills" as well as those continuing care.

(c) 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~~ therapeutic substitution.

~~(d) 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)~~(d) Pharmacists. When a pharmacist dispenses a therapeutically equivalent drug ~~product~~ or pharmaceutical or interchangeable biological product, there shall be no additional liability imposed on the prescriber ~~who authorizes that product selection,~~ or on the pharmacist performing therapeutic substitution or dispensing the product selection from a physician's oral or written order.

~~(f)~~(e) 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)~~(f) Biological-product selection. The director shall permit substitution of ~~a less expensive~~ an equivalent biological product, as defined in § 5-19.1-2, for ~~a~~ another 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.~~

(g) Device product selection. The director shall permit substitution of a device, or supply as defined in § 5-19.1-2, for a prescribed product only if said 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. Such examples suitable for interchange include, but are not limited to, supplies and devices used to monitor glucose, administer insulin or another pharmacologic product.

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

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EXPLANATION

BY THE LEGISLATIVE COUNCIL

OF

A N A C T

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

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This act would amend the types of products which pharmacists may prescribe as substitute drugs or products to include "devices and supplies" and "therapeutically equivalent drugs and pharmaceuticals".

This act would take effect on January 1, 2026.

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