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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. 2016

A N A C T

RELATING TO BUSINESSES AND PROFESSIONS - PHARMACIES

Introduced By: Senators Coyne, Lombardo, Cote, DiPalma, and Lombardi

Date Introduced: March 10, 2016

Referred To: Senate Health & Human Services

It is enacted by the General Assembly as follows:

SECTION 1. Section 5-19.1-2 of the General Laws in Chapter 5-19.1 entitled "Pharmacies" is hereby amended to read as follows:

5-19.1-2. Definitions. – (a) "Biological product" means a "biological product" as defined in the "Public Health Service Act", 42 U.S.C. §262.

~~(a)~~(b) "Board" means the Rhode Island board of pharmacy.

~~(b)~~(c) "Change of ownership" means:

(1) In the case of a pharmacy, manufacturer, or wholesaler that is a partnership, any change that results in a new partner acquiring a controlling interest in the partnership;

(2) In the case of a pharmacy, manufacturer, or wholesaler that is a sole proprietorship, the transfer of the title and property to another person;

(3) In the case of a pharmacy, manufacturer, or wholesaler that is a corporation:

(i) A sale, lease exchange, or other disposition of all, or substantially all, of the property and assets of the corporation; or

(ii) A merger of the corporation into another corporation; or

(iii) The consolidation of two (2) or more corporations resulting in the creation of a new corporation; or

(iv) In the case of a pharmacy, manufacturer, or wholesaler that is a business corporation, any transfer of corporate stock that results in a new person acquiring a controlling interest in the corporation; or

(v) In the case of a pharmacy, manufacturer, or wholesaler that is a non-business corporation, any change in membership that results in a new person acquiring a controlling vote in the corporation.

~~(c)~~(d) "Compounding" means the act of combining two (2) or more ingredients as a result of a practitioner's prescription or medication order occurring in the course of professional practice based upon the individual needs of a patient and a relationship between the practitioner, patient, and pharmacist. Compounding does not mean the routine preparation, mixing, or assembling of drug products that are essentially copies of a commercially available product. Compounding shall only occur in the pharmacy where the drug or device is dispensed to the patient or caregiver and includes the preparation of drugs or devices in anticipation of prescription orders based upon routine, regularly observed prescribing patterns.

~~(d)~~(e) "Controlled substance" means a drug or substance, or an immediate precursor of such drug or substance, so designated under or pursuant to the provisions of chapter 28 of title 21.

~~(e)~~(f) "Deliver" or "delivery" means the actual, constructive, or attempted transfer from one person to another of a drug or device, whether or not there is an agency relationship.

~~(f)~~(g) "Device" means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended:

(1) For use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or

(2) To affect the structure or any function of the body of man or other animals.

~~(g)~~(h) "Director" means the director of the Rhode Island state department of health.

~~(h)~~(i) "Dispense" means the interpretation of a prescription or order for a drug, biological, or device and, pursuant to that prescription or order, the proper selection, measuring, compounding, labeling, or packaging necessary to prepare that prescription or order for delivery or administration.

~~(i)~~(j) "Distribute" means the delivery of a drug or device other than by administering or dispensing.

~~(j)~~(k) "Drug" means:

(1) Articles recognized in the official United States Pharmacopoeia or the Official Homeopathic Pharmacopoeia of the U.S.;

(2) Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man, woman, or other animals;

(3) Substances (other than food) intended to affect the structure or any function of the body of man, woman, or other animals; or

(4) Substances intended for use as a component of any substances specified in subdivision (1), (2), or (3) of this subsection, but not including devices or their component parts or accessories.

~~(k)~~(l) "Equivalent and interchangeable" means a drug, excluding a biological product, having the same generic name, dosage form, and labeled potency, meeting standards of the United States Pharmacopoeia or National Formulary, or their successors, if applicable, and not found in violation of the requirements of the United States Food and Drug Administration, or its successor agency, or the Rhode Island department of health.

(m) "Interchangeable biological product" means a biological product that the United States Food and Drug Administration has:

(1) Licensed and determined meets the standards for interchangeability pursuant to 42 U.S.C. §262(k)(4) or lists of licensed biological products with reference product exclusivity and biosimilarity or interchangeability evaluations; or

(2) Determined is therapeutically equivalent as set forth in the latest edition of or supplement to the United States Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations.

~~(l)~~(n) "Intern" means:

(1) A graduate of an American Council on Pharmaceutical Education (ACPE)-accredited program of pharmacy;

(2) A student who is enrolled in at least the first year of a professional ACPE-accredited program of pharmacy; or

(3) A graduate of a foreign college of pharmacy who has obtained full certification from the FPGEC (Foreign Pharmacy Graduate Equivalency Commission) administered by the National Association of Boards of Pharmacy.

~~(m)~~(o) "Limited function test" means those tests listed in the federal register under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as waived tests. For the purposes of this chapter, limited function test shall include only the following: blood glucose, hemoglobin Alc, cholesterol tests, and/or other tests that are classified as waived under CLIA and are approved by the United States Food and Drug Administration for sale to the public without a prescription in the form of an over-the-counter test kit.

~~(n)~~(p) "Legend drugs" means any drugs that are required by any applicable federal or state law or regulation to be dispensed on prescription only or are restricted to use by practitioners only.

~~(o)~~(q) "Manufacture" means the production, preparation, propagation, compounding, or

processing of a drug or other substance or device or the packaging or repackaging.

~~(p)~~(r) "Non-legend" or "nonprescription drugs" means any drugs that may be lawfully sold without a prescription.

~~(q)~~(s) "Person" means an individual, corporation, government, subdivision or agency, business trust, estate, trust, partnership or association, or any other legal entity.

~~(r)~~(t) "Pharmaceutical care" is the provision of drugs and other pharmaceutical services intended to achieve outcomes related to cure or prevention of a disease elimination or reduction of a patient's symptoms or arresting or slowing of a disease process. "Pharmaceutical care" includes the judgment of a pharmacist in dispensing an equivalent and interchangeable drug or device in response to a prescription after appropriate communication with the prescriber and the patient.

~~(s)~~(u) "Pharmacist in charge" means a pharmacist licensed in this state as designated by the owner as the person responsible for the operation of a pharmacy in conformance with all laws and regulations pertinent to the practice of pharmacy and who is personally in full and actual charge of such pharmacy and personnel.

~~(t)~~(v) "Pharmacy" means that portion or part of a premise where prescriptions are compounded and dispensed, including that portion utilized for the storage of prescription or legend drugs.

~~(u)~~(w) "Pharmacy technician" means an individual who meets minimum qualifications established by the board, that are less than those established by this chapter as necessary for licensing as a pharmacist, and who works under the direction and supervision of a licensed pharmacist.

~~(v)~~(x) "Practice of pharmacy" means the interpretation, evaluation, and implementation of medical orders; the dispensing of prescription drug orders; participation in drug and device selection; the compounding of prescription drugs; drug regimen reviews and drug or drug-related research; the administration of adult immunizations pursuant to a valid prescription or physician-approved protocol and in accordance with regulations, to include training requirements as promulgated by the department of health; the administration of all forms of influenza immunizations to individuals between the ages of nine (9) years and eighteen (18) years, inclusive, pursuant to a valid prescription or prescriber-approved protocol, in accordance with the provisions of § 5-19.1-31 and in accordance with regulations, to include necessary training requirements specific to the administration of influenza immunizations to individuals between the ages of nine (9) years and eighteen (18) years, inclusive, as promulgated by the department of health; provision of patient counseling and the provision of those acts or services necessary to

provide pharmaceutical care; and/or the responsibility for the supervision for compounding and labeling of drugs and devices (except labeling by a manufacturer, repackager, or distributor of non-prescription drugs and commercially packaged legend drugs and devices), proper and safe storage of drugs and devices, and maintenance of proper records for them; and the performance of clinical laboratory tests, provided such testing is limited to limited-function tests as defined herein. Nothing in this definition shall be construed to limit or otherwise affect the scope of practice of any other profession.

~~(w)~~(y) "Practitioner" means a physician, dentist, veterinarian, nurse, or other person duly authorized by law in the state in which they practice to prescribe drugs.

~~(x)~~(z) "Preceptor" means a pharmacist registered to engage in the practice of pharmacy in this state who has the responsibility for training interns.

~~(y)~~(aa) "Prescription" means an order for drugs or devices issued by the practitioner duly authorized by law in the state in which he or she practices to prescribe drugs or devices in the course of his or her professional practice for a legitimate medical purpose.

~~(z)~~(bb) "Wholesaler" means a person who buys drugs or devices for resale and distribution to corporations, individuals, or entities other than consumers.

SECTION 2. Chapter 5-19.1 of the General Laws entitled "Pharmacies" is hereby amended by adding thereto the following section:

5-19.1-19.1. Pharmacists - Substitution of biological products. – (a) Pharmacists when dispensing a prescription for any biological product shall, unless requested otherwise by the individual presenting the prescription in writing, substitute such product with an interchangeable biological product in accordance with the provisions of §21-31-16.1(g). No substitution under this section shall be allowed if the prescribing physician orders the pharmacist to dispense as brand name necessary on the prescription form, or if the prescriber gives oral direction to that effect to the dispensing pharmacist. The requirements of this section shall not apply to an order to dispense a biological product for immediate administration to a licensed hospital, nursing facility, or hospice facility in-patient. The pharmacist will make a biological product selection from approved interchangeable prescription biological products in accordance with §21-31-16.1(g). When a biological product selection is made, the pharmacist shall inform the patient of the selection made and shall indicate the product dispensed on the written prescription or on the oral prescription, which has been reduced to writing, or product information may be maintained on a computerized system if information is readily retrievable.

(b) Within five (5) business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescriber the

specific product provided to the patient, including the name of the product and the manufacturer.

(c) The communication shall be conveyed by making an entry electronically accessible to the prescriber through:

(1) An interoperable electronic medical records system;

(2) An electronic prescribing technology;

(3) A pharmacy benefit management system; or

(4) A pharmacy record.

(d) Entry into an electronic records system as described in this subsection is presumed to provide notice to the prescriber. Otherwise, the pharmacist shall communicate the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission, or other prevailing means, provided that the communication shall not be required where:

(1) There is no interchangeable biological product for the product prescribed approved by the United States Food and Drug Administration; or

(2) A refill prescription is not changed from the product dispensed on the prior filling of the prescription.

SECTION 3. 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. --~~ Substitution of generic drugs and biological products. -- (a) ~~Product selection.~~ 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) Appropriations. - The director shall provide necessary space, personnel, and material

to carry out the provisions of this section.

(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.

(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) 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) 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) 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.

SECTION 4. This act shall take effect upon passage.

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EXPLANATION

BY THE LEGISLATIVE COUNCIL

OF

A N A C T

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This act would add biological products and interchangeable biological products to the medications pharmacies may dispense, and would regulate the procedures for dispensing and substitution.

This act would take effect upon passage.

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