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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. 2023

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A N A C T

RELATING TO BUSINESSES AND PROFESSIONS -- PHARMACIES

Introduced By: Senators Miller, DiPalma, Euer, DiMario, Lawson, Valverde, Murray, and Kallman
Date Introduced: March 07, 2023

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.

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

(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.

(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.

(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.

(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.

(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 humans or other animals; or

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

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

(i) "Dispense" means the interpretation of a prescription or order for a drug, biological product, 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.

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

(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 humans or other animals;

(3) Substances (other than food) intended to affect the structure, or any function, of the

body of humans or other animals; or

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

(l) "HIV" means human immunodeficiency virus.

(m) "HIV prevention drug" means a drug approved by the United States Food and Drug Administration for the prevention of HIV, including, but not limited to, pre-exposure prophylaxis.

~~(l)~~(n) "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)~~(o) "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.

~~(n)~~(p) "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.

~~(o)~~(q) "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.

~~(p)~~(r) "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 A1c, 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.

~~(q)~~(s) "Manufacture" means the production, preparation, propagation, compounding, or processing of a drug or other substance or device or the packaging or repackaging.

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

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

~~(t)~~(v) "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.

~~(u)~~(w) "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.

~~(v)~~(x) "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.

~~(w)~~(y) "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.

~~(x)~~(z) "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 and, medications approved by the department of health in consultation with the board of pharmacy for administration by a pharmacist except as provided by § 5-25-7, 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; the responsibility for the supervision for compounding and labeling of drugs and devices (except labeling by a manufacturer, repackager, or distributor of nonprescription 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.

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

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

(cc) "Pre-exposure prophylaxis" means a drug or drug combination that is taken or administered to reduce the risk of HIV acquisition and meets the same clinical eligibility recommendations provided in current guidelines of the federal Centers for Disease Control and Prevention.

(aa)(dd) "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.

~~(bb)~~(ee) "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:

5-19.1-19.2. Pharmacists -- Prescribing, dispensing and administering PrEP.

(a) A licensed pharmacist may prescribe, dispense or administer HIV prevention drugs in accordance with regulations promulgated by the department of health as set forth in this section.

(b) A licensed pharmacist may prescribe, dispense or administer HIV prevention drugs according to United States Food and Drug Administration guidance and product labeling if the patient:

(1) Is HIV negative, as documented by a negative HIV test result obtained within the previous seven (7) days from an HIV antigen and antibody test or antibody-only test or from a rapid, point-of-care fingerstick blood test approved by the United States Food and Drug Administration; provided, however, that if the patient does not provide evidence of a negative HIV

test in accordance with this clause, the pharmacist may order an HIV test prior to prescribing, dispensing or administering the drugs; provided further, that if the test results are not transmitted directly to the pharmacist, the pharmacist shall verify the test results to the pharmacist's satisfaction prior to prescribing, dispensing or administering the drugs; and provided further, that if the patient tests positive for HIV infection, the pharmacist or person administering the test shall direct the patient to a primary care provider and provide the patient with a list of providers and clinics in the region;

(2) Does not report any signs or symptoms of acute HIV infection on a self-reported checklist of acute HIV infection signs and symptoms; and

(3) Does not report taking any contraindicated medication.

(c) A licensed pharmacist that prescribes, dispenses or administers HIV prevention drugs shall:

(1) Provide counseling to the patient on the ongoing use of pre-exposure prophylaxis, which may include education about side effects, safety during pregnancy and breastfeeding, adherence to recommended dosing and the importance of timely testing and treatment, as applicable, for HIV, renal function, hepatitis B, hepatitis C, sexually transmitted infections and pregnancy for individuals of child-bearing capacity;

(2) Notify the patient that the patient is required to be seen by a primary care provider to receive subsequent prescriptions for pre-exposure prophylaxis and that a pharmacist shall not furnish a sixty (60) day supply of pre-exposure prophylaxis to a single patient more than once every two (2) years:

(3) Document, to the extent possible, the services provided to the patient by the pharmacist in the patient's record in the record system maintained by the pharmacy and maintain records of pre-exposure prophylaxis furnished to each patient; and

(4) Notify the patient's primary care provider that the pharmacist completed the requirements specified in this subsection; provided, however that, if the patient does not have a primary care provider or refuses consent to notify the patient's primary care provider, the pharmacist shall provide the patient a list of physicians and surgeons, clinics or other health care service providers to contact regarding ongoing care for pre-exposure prophylaxis.

(d) The department of health shall promulgate regulations to establish statewide drug therapy protocols for prescribing, dispensing and administering pre-exposure prophylaxis and other HIV prevention drugs approved by the United States Food and Drug Administration that are consistent with federal Centers for Disease Control and Prevention guidelines not later than six (6) months after the effective date of this act. The regulations shall include, but not be limited to, rules

stating that a pharmacist shall not furnish a sixty (60) day supply of pre-exposure prophylaxis to a single patient more than once every two (2) years.

SECTION 3. This act shall take effect upon passage.

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EXPLANATION

BY THE LEGISLATIVE COUNCIL

OF

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RELATING TO BUSINESSES AND PROFESSIONS -- PHARMACIES

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This act would provide for the prescribing, dispensing and the administering human immunodeficiency virus (HIV) prevention drugs.

This act would take effect upon passage.

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