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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 Doyle, Nesselbush, and DiPalma

Date Introduced: February 25, 2016

Referred To: Senate Health & Human Services

It is enacted by the General Assembly as follows:

SECTION 1. Sections 5-19.1-2 and 5-19.1-31 of the General Laws in Chapter 5-19.1 entitled "Pharmacies" are hereby amended to read as follows:

5-19.1-2. Definitions. -- (a) "Board" means the Rhode Island board of pharmacy.

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

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

(j) "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) "Equivalent and interchangeable" means 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.

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

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

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

(r) "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) "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) "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) "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) "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) "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) "Preceptor" means a pharmacist registered to engage in the practice of pharmacy in

this state who has the responsibility for training interns.

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

5-19.1-31. ~~Administration of influenza immunizations to individuals between the ages of nine (9) years and eighteen (18) years, inclusive. --~~ Administration of immunizations to individuals between the ages of nine (9) years and eighteen (18) years, inclusive. -- (a) Parental consent shall be required for all pharmacist-administered immunizations for individuals under the age of eighteen (18) years.

(b) The department of health shall require a pharmacist who is authorized to administer ~~influenza~~ immunizations to individuals between the ages of nine (9) years and eighteen (18) years, inclusive, pursuant to § 5-19.1-2, to electronically report to the department all immunizations administered within seven (7) days of administration in the format and for the populations required by the department.

(c) (1) The department of health shall require a pharmacist who is authorized to administer ~~influenza~~ immunizations to individuals between the ages of nine (9) years and eighteen (18) years, inclusive, pursuant to § 5-19.1-2 to provide notification of a patient's immunization to the patient's primary care provider, if known, within fourteen (14) days of administration.

(2) The department of health's rules and regulations shall include provisions to ensure that the administering pharmacist make a good faith effort to obtain information relating to the identity of a patient's primary care provider or primary care practice, for the purposes of fulfilling the reporting requirements of subdivision (c)(1) herein. If a patient does not have an existing relationship with a primary care provider or primary care practice, the administering pharmacist shall proceed with the reporting requirements contained in subsection (b) herein.

SECTION 2. 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 expand a pharmacist's immunization authority for individuals between the ages of nine (9) and eighteen (18) by permitting the administration of a broader array of vaccines.

This act would take effect upon passage.

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