2014 -- S 2518

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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. 2014

A N A C T

RELATING TO BUSINESSES AND PROFESSIONS-PHARMACIES

Introduced By: Senators Doyle, Nesselbush, P Fogarty, and Lynch

Date Introduced: February 27, 2014

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

(b) "Change of ownership" means:

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

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

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

(v) In the case of a pharmacy, manufacturer, or wholesaler which is a non-business corporation, any change in membership, which 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 and section 5-19-1(16), 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) "Legend drugs" means any drugs, which 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.

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

(o) "Non-legend" or "nonprescription drugs" means any drugs, which may be lawfully sold without a prescription.

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

(q) "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.

(r) "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.

(s) "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.

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

(u) "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 section 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. Nothing in this definition shall be construed to limit or otherwise affect the scope of practice of any other profession.

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

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

(x) "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.

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

SECTION 2. This act shall take effect upon passage.

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EXPLANATION

BY THE LEGISLATIVE COUNCIL

OF

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This act would include "clinical pharmacist practitioners" within the definition of "practitioner" for purposes of presenting drugs.

This act would take effect upon passage.

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