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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. 2015

A N A C T

RELATING TO BUSINESSES AND PROFESSIONS - PHARMACIES

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

Date Introduced: February 12, 2015

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 § 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) "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.

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

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

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

~~(q)~~(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.

~~(r)~~(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.

~~(s)~~(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.

~~(t)~~(u) "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)~~(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.

~~(v)~~(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.

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

~~(x)~~(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.

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

SECTION 2. Section 5-19.2-2 of the General Laws in Chapter 5-19.2 entitled "Collaborative Pharmacy Practice" is hereby amended to read as follows:

5-19.2-2. Definitions. -- (a) "Collaborative practice agreement" is a written and signed agreement, entered into voluntarily, between a pharmacist with advanced training and experience relevant to the scope of collaborative practice and one or more physicians that defines the collaborative pharmacy practice in which the pharmacist and physician(s) propose to engage. Collaborative practice agreements shall be made in the best interest of public health.

(b) "Collaborative practice committee" shall consist of six (6) individuals: three (3) individuals to be appointed by the board of pharmacy from nominees provided by the Rhode Island Pharmacists Association; three (3) individuals to be appointed by the board of medical licensure and discipline from nominees provided by the Rhode Island Medical Society. The collaborative practice committee shall advise the director on all issues pertinent to the regulation of collaborative practice agreements.

(c) "Collaborative pharmacy practice" is that practice of pharmacy whereby a pharmacist with advanced training and experience relevant to the scope of collaborative practice agrees to work in collaboration with one or more physicians for the purpose of drug therapy management of patients, such management to be pursuant to a protocol or protocols authorized by the physician(s) and subject to conditions and/or limitations as set forth by the department. A health care professional who has prescribing privileges and is employed by a collaborating physician may be in such an agreement.

(d) "Drug therapy management" means the review, in accordance with a collaborative practice agreement, of drug therapy regimen or regimens of patients by a pharmacist for the purpose of rendering advice to one or more physicians that are party to the agreement, or their physician designees, regarding adjustment of the regimen. Decisions involving drug therapy management shall be made in the best interests of the patient. In accordance with a collaborative practice agreement, drug therapy management may include:

(1) Modifying and managing drug therapy;

(2) Collecting and reviewing patient histories;

(3) Obtaining and checking vital signs, including pulse, temperature, blood pressure, and

respiration; and

(4) Under the supervision of, or in direct consultation with a physician, ordering and evaluating the results of laboratory tests directly related to drug therapy when performed in accordance with approved protocols applicable to the practice setting and providing such evaluation does not include any diagnostic component.

(e) "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.

~~(e)~~(f) "Pharmacist with advanced training and experience relevant to the scope of collaborative practice" means a licensed pharmacist in this state with post-graduate educational training. Such training shall include, but not limited to, residency training, board certification, certification from an accredited professional organization educational institution, or any other continuing education provider approved by the director of health, relevant to the proposed scope of the collaborative practice agreement.

~~(f)~~(g) "Practice of pharmacy" means the interpretation, evaluation, and implementation of medical orders; including the performance of clinical laboratory tests provided such testing is ~~conducted in conformity with the federal Clinical Laboratories Improvement Act, as amended, 42 U.S.C. § 263a~~ limited to limited function tests as defined herein; the dispensing of prescription drug orders; participation in drug and device selection; drug regiment reviews and drug or drug related research; provision of patient counseling and the provision of those acts or services necessary to provide pharmaceutical care; drug therapy management pursuant to a collaborative practice agreement; and 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.

SECTION 3. Chapter 5-19.1 of the General Laws entitled "Pharmacies" is hereby amended by adding thereto the following section:

5-19.1-32. Limited function tests. – (a) Upon receiving consent from the patient, a pharmacist performing a limited function test in accordance with this chapter shall report test results to the patient's primary care practitioner, if known, within a reasonable period of time. In the event that a patient with an abnormal test result does not have an existing relationship with a

primary care practitioner, the pharmacist shall make efforts to refer the patient to a primary care practitioner, practice, health center, or clinic.

(b)(1) The pharmacy shall develop policies and procedures for emergency situations related to the provision of limited function health tests, to include the prompt reporting of test results to a patient's primary care practitioner, if known.

(2) The department shall promulgate rules and regulations to carry out the provisions of this section. The department's rules and regulations may include the following:

(i) Requirements for the pharmacist to inform the patient that the limited function test results are intended for informational and educational purposes, rather than diagnostic purposes; and

(ii) Requirements ensuring appropriate temperature and environmental controls to maintain the efficacy of the limited function test kit.

SECTION 4. Section 23-16.2-3 of the General Laws in Chapter 23-16.2 entitled "Laboratories" is hereby amended to read as follows:

23-16.2-3. Application of law -- Exceptions. -- The provisions of this chapter shall apply to all laboratories and stations performing analytical or clinical laboratory services or specimens in this state except:

(1) A laboratory maintained by a hospital licensed under chapter 17 of this title, or by a licensed physician or group of licensed physicians who make the tests referred to in § 23-16.2-2 personally and solely in connection with the treatment of their own patients; however, an independent laboratory which makes the tests on its own responsibility for a single physician or group of physicians is subject to this chapter.

(2) Any temporary or ad hoc health promotion or screening program conducted for the general public which offers generally accepted mass screening procedures; provided the health promotion or screening program is conducted pursuant to a permit issued by the department of health.

(3) Any person performing only limited function tests as defined in regulation by the director.

(4) Licensed pharmacists performing limited function tests as defined in § 5-19.1-2(m).

SECTION 5. Section 23-16.3-4 of the General Laws in Chapter 23-16.3 entitled "Clinical Laboratory Science Practice" is hereby amended to read as follows:

23-16.3-4. Exceptions. -- This chapter shall not apply to:

(1) Any person performing clinical laboratory tests within the scope of his or her practice and for which he or she is licensed pursuant to any other provisions of the general laws.

(2) Clinical laboratory science practitioners employed by the United States government or any bureau, division, or agency of the United States government while in the discharge of the employee's official duties.

(3) Clinical laboratory science practitioners engaged in teaching or research, provided that the results of any examination performed are not used in health maintenance, diagnosis, or treatment of disease.

(4) Students or trainees enrolled in a clinical laboratory science education program provided that these activities constitute a part of a planned course in the program, that the persons are designated by title such as intern, trainee, or student, and the persons work directly under the supervision of an individual licensed by this state to practice laboratory science.

(5) Individuals performing limited function tests.

(6) Licensed pharmacists performing limited function tests as defined in § 5-19.1-2(m).

SECTION 6. 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 authorize pharmacists to perform limited function clinical laboratory tests.

This act would take effect upon passage.

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