

**2015 -- H 5497 SUBSTITUTE A**

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LC000979/SUB A/2  
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**STATE OF RHODE ISLAND**

**IN GENERAL ASSEMBLY**

**JANUARY SESSION, A.D. 2015**

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A N A C T

RELATING TO BUSINESSES AND PROFESSIONS - PHARMACIES

Introduced By: Representatives Serpa, and Fellela

Date Introduced: February 12, 2015

Referred To: House Health, Education & Welfare

It is enacted by the General Assembly as follows:

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

3           **5-19.1-2. Definitions.** -- (a) "Board" means the Rhode Island board of pharmacy.

4           (b) "Change of ownership" means:

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

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

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

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

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

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

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

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

1 vote in the corporation.

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

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

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

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

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

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

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

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

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

26 (j) "Drug" means:

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

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

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

33 (4) Substances intended for use as a component of any substances specified in  
34 subdivision (1), (2), or (3) of this subsection ~~and § 5-19-1(16)~~, but not including devices or their

1 component parts or accessories.

2 (k) "Equivalent and interchangeable" means having the same generic name, dosage form,  
3 and labeled potency, meeting standards of the United States Pharmacopoeia or National  
4 Formulary, or their successors, if applicable, and not found in violation of the requirements of the  
5 United States Food and Drug Administration, or its successor agency, or the Rhode Island  
6 department of health.

7 (l) "Intern" means:

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

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

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

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

21 ~~(m)~~(n) "Legend drugs" means any drugs, which are required by any applicable federal or  
22 state law or regulation to be dispensed on prescription only or are restricted to use by practitioners  
23 only.

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

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

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

30 ~~(p)~~(r) "Pharmaceutical care" is the provision of drugs and other pharmaceutical services  
31 intended to achieve outcomes related to cure or prevention of a disease, elimination or reduction  
32 of a patient's symptoms, or arresting or slowing of a disease process. "Pharmaceutical care"  
33 includes the judgment of a pharmacist in dispensing an equivalent and interchangeable drug or  
34 device in response to a prescription, after appropriate communication with the prescriber and the

1 patient.

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

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

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

12 ~~(+)~~(v) "Practice of pharmacy" means the interpretation, evaluation, and implementation  
13 of medical orders; the dispensing of prescription drug orders; participation in drug and device  
14 selection; the compounding of prescription drugs; drug regimen reviews and drug or drug related  
15 research; the administration of adult immunizations pursuant to a valid prescription or physician  
16 approved protocol and in accordance with regulations, to include training requirements as  
17 promulgated by the department of health; the administration of all forms of influenza  
18 immunizations to individuals between the ages of nine (9) years and eighteen (18) years,  
19 inclusive, pursuant to a valid prescription or prescriber approved protocol, in accordance with the  
20 provisions of § 5-19.1-31 and in accordance with regulations, to include necessary training  
21 requirements specific to the administration of influenza immunizations to individuals between the  
22 ages of nine (9) years and eighteen (18) years, inclusive, as promulgated by the department of  
23 health; provision of patient counseling and the provision of those acts or services necessary to  
24 provide pharmaceutical care; and/or the responsibility for the supervision for compounding and  
25 labeling of drugs and devices (except labeling by a manufacturer, repackager, or distributor of  
26 non-prescription drugs and commercially packaged legend drugs and devices), proper and safe  
27 storage of drugs and devices, and maintenance of proper records for them; and the performance of  
28 clinical laboratory tests, provided such testing is limited to limited function tests as defined  
29 herein. Nothing in this definition shall be construed to limit or otherwise affect the scope of  
30 practice of any other profession.

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

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

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

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

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

8           **5-19.2-2. Definitions.** -- (a) "Collaborative practice agreement" is a written and signed  
9 agreement, entered into voluntarily, between a pharmacist with advanced training and experience  
10 relevant to the scope of collaborative practice and one or more physicians that defines the  
11 collaborative pharmacy practice in which the pharmacist and physician(s) propose to engage.  
12 Collaborative practice agreements shall be made in the best interest of public health.

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

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

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

- 32           (1) Modifying and managing drug therapy;  
33           (2) Collecting and reviewing patient histories;  
34           (3) Obtaining and checking vital signs, including pulse, temperature, blood pressure, and

1 respiration; and

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

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

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

18 ~~(f)~~(g) "Practice of pharmacy" means the interpretation, evaluation, and implementation  
19 of medical orders; including the performance of clinical laboratory tests provided such testing is  
20 ~~conducted in conformity with the federal Clinical Laboratories Improvement Act, as amended, 42~~  
21 ~~U.S.C. § 263a~~ limited to limited function tests as defined herein; the dispensing of prescription  
22 drug orders; participation in drug and device selection; drug regimen reviews and drug or drug  
23 related research; provision of patient counseling and the provision of those acts or services  
24 necessary to provide pharmaceutical care; drug therapy management pursuant to a collaborative  
25 practice agreement; and the responsibility for the supervision for compounding and labeling of  
26 drugs and devices (except labeling by a manufacturer, repackager, or distributor of  
27 nonprescription drugs and commercially packaged legend drugs and devices), proper and safe  
28 storage of drugs and devices, and maintenance of proper records for them.

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

31 **5-19.1-32. Limited function tests.** – (a) Upon receiving consent from the patient, a  
32 pharmacist performing a limited function test in accordance with this chapter shall report test  
33 results to the patient's primary care practitioner, if known, within a reasonable period of time. In  
34 the event that a patient with an abnormal test result does not have an existing relationship with a

1 [primary care practitioner, the pharmacist shall make efforts to refer the patient to a primary care](#)  
2 [practitioner, practice, health center, or clinic.](#)

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

6 [\(2\) The department shall promulgate rules and regulations to carry out the provisions of](#)  
7 [this section. The department's rules and regulations may include the following:](#)

8 [\(i\) Requirements for the pharmacist to inform the patient that the limited function test](#)  
9 [results are intended for informational and educational purposes, rather than diagnostic purposes;](#)  
10 [and](#)

11 [\(ii\) Requirements ensuring appropriate temperature and environmental controls to](#)  
12 [maintain the efficacy of the limited function test kit.](#)

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

15 **23-16.2-3. Application of law -- Exceptions. --** The provisions of this chapter shall  
16 apply to all laboratories and stations performing analytical or clinical laboratory services or  
17 specimens in this state except:

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

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

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

29 [\(4\) Licensed pharmacists performing limited function tests as defined in § 5-19.1-2\(m\).](#)

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

32 **23-16.3-4. Exceptions. --** This chapter shall not apply to:

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

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

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

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

11           (5) Individuals performing limited function tests.

12           [\(6\) Licensed pharmacists performing limited function tests as defined in § 5-19.1-2\(m\).](#)

13           SECTION 6. This act shall take effect upon passage.

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LC000979/SUB A/2  
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EXPLANATION  
BY THE LEGISLATIVE COUNCIL  
OF  
A N A C T  
RELATING TO BUSINESSES AND PROFESSIONS - PHARMACIES

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- 1 This act would authorize pharmacists to perform limited function clinical laboratory tests.
- 2 This act would take effect upon passage.

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