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LC00794

STATE OF RHODE ISLAND

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2011

A N A C T

RELATING TO BUSINESSES AND PROFESSIONS -- PHARMACIES

Introduced By: Representative Patricia A. Serpa

Date Introduced: February 03, 2011

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 section 5-19-1(16), but not including devices or

1 their 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) "Legend drugs" means any drugs, which are required by any applicable federal or
16 state law or regulation to be dispensed on prescription only or are restricted to use by practitioners
17 only.

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

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

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

24 (q) "Pharmaceutical care" is the provision of drugs and other pharmaceutical services
25 intended to achieve outcomes related to cure or prevention of a disease, elimination or reduction
26 of a patient's symptoms, or arresting or slowing of a disease process. "Pharmaceutical care"
27 includes the judgment of a pharmacist in dispensing an equivalent and interchangeable drug or
28 device in response to a prescription, after appropriate communication with the prescriber and the
29 patient.

30 (r) "Pharmacist-in-charge" means a pharmacist licensed in this state as designated by the
31 owner as the person responsible for the operation of a pharmacy in conformance with all laws and
32 regulations pertinent to the practice of pharmacy and who is personally in full and actual charge
33 of such pharmacy and personnel.

34 (s) "Pharmacy" means that portion or part of a premise where prescriptions are

1 compounded and dispensed, including that portion utilized for the storage of prescription or
2 legend drugs.

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

6 (u) "Practice of pharmacy" means the interpretation, evaluation, and implementation of
7 medical orders; the dispensing of prescription drug orders; participation in drug and device
8 selection; the compounding of prescription drugs; drug regimen reviews and drug or drug related
9 research; the administration of adult immunizations and the administration of all forms of
10 influenza immunizations to individuals nine (9) years of age and older, pursuant to a valid
11 prescription or physician approved protocol and in accordance with regulations, to include
12 training requirements and necessary training requirements specific to the administration of
13 influenza immunizations to individuals nine (9) years of age and older as promulgated by the
14 department of health administration of other immunizations to individuals age nine (9) years and
15 older, pursuant to a valid prescription, in accordance with the provisions of section 5-19.1-31 and
16 in accordance with regulations, to include necessary training requirements specific to the
17 administration of immunizations to individuals nine (9) years of age and older, as promulgated by
18 the department of health; provision of patient counseling and the provision of those acts or
19 services necessary to provide pharmaceutical care; and/or the responsibility for the supervision
20 for compounding and labeling of drugs and devices (except labeling by a manufacturer,
21 repackager, or distributor of non-prescription drugs and commercially packaged legend drugs and
22 devices), proper and safe storage of drugs and devices, and maintenance of proper records for
23 them. Nothing in this definition shall be construed to limit or otherwise affect the scope of
24 practice of any other profession.

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

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

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

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

34 SECTION 2. Chapter 5-19.1 of the General Laws entitled "Pharmacies" is hereby

1 amended by adding thereto the following section:

2 **5-19.1-31. Administration of immunizations to individuals nine (9) years of age and**

3 **older. -- (a) The department of health shall require a pharmacist who is authorized to administer**
4 **immunizations to individuals nine (9) years of age and older pursuant to section 5-19.1-2, to**
5 **electronically report to the department all immunizations administered within seven (7) days of**
6 **administration in the format and for the populations required by the department.**

7 (b) The department of health shall require a pharmacist who is authorized to administer
8 immunizations to individuals nine (9) years of age and older pursuant to section 5-19.1-2 to
9 provide notification of a patient's immunization to the patient's primary care provider, if known,
10 within fourteen (14) days of administration.

11 (c) The department of health's rules and regulation regarding administration of
12 immunizations to individuals nine (9) years of age and older shall include provisions to ensure
13 that the administering pharmacist make a good faith effort to obtain information relating to the
14 identity of a patient's primary care provider or primary care practice, for the purposes of fulfilling
15 the reporting requirements of subsection (b) herein. If a patient does not have an existing
16 relationship with a primary care provider or primary care practice, the administering pharmacist
17 shall proceed with the reporting requirements contained in subsection (a) herein.

18 SECTION 3. This act shall take effect upon passage.

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EXPLANATION
BY THE LEGISLATIVE COUNCIL
OF
A N A C T
RELATING TO BUSINESSES AND PROFESSIONS – PHARMACIES

1 This act would allow the administration of immunizations by a pharmacy to adults and
2 children nine (9) years of age and older. This act would also require a pharmacist who is
3 authorized to administer immunizations, to electronically report to the department of health all
4 immunizations administered within seven (7) days of administration in the format and for the
5 populations required by the department.

6 This act would take effect upon passage.

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