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STATE OF RHODE ISLAND

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2014

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A N A C T

RELATING TO BUSINESS AND PROFESSIONS -- PHARMACIES

Introduced By: Representative Michael J. Marcello

Date Introduced: March 06, 2014

Referred To: House Health, Education & Welfare

It is enacted by the General Assembly as follows:

1 SECTION 1. Section 5-19.1-18 of the General Laws in Chapter 5-19.1 entitled
2 "Pharmacies" is hereby amended to read as follows:

3 **5-19.1-18. Necessity of prescription label.** -- To every box, bottle, jar, tube or other
4 container of a prescription, which is dispensed, a label shall be attached, the contents of which,
5 shall be defined by the board by regulation, except that prescription drugs compounded for use in
6 a healthcare facility or physician office shall be labeled as set forth in § 5-19.1-32.

7 SECTION 2. Chapter 5-19.1 of the General Laws entitled "Pharmacies" is hereby
8 amended by adding thereto the following section:

9 **5-19.1-32. Labeling of compounded drugs used in facility or office.** -- (a) Prescription
10 drugs that are not commercially available may be compounded for a healthcare facility, as
11 defined in § 23-17-2, or physician's office use, but shall not be resold. All compounding shall be
12 done in compliance with the United States Pharmacopeia and as defined by the board.

13 (b) The compounded drug product shall bear the label of the pharmacy responsible for
14 compounding and dispensing the product directly to the patient for administration, and the
15 prescription shall be filled at that pharmacy. Compounded prescription labels shall include the
16 following information:

17 (1) The name of the prescriber;

18 (2) The name and address of the pharmacy;

19 (3) The name of the drug dispensed in accordance with chapter 31 of title 21;

- 1 (4) Quantity and strength of the drug dispensed;
- 2 (5) The date of dispensing;
- 3 (6) The prescription number;
- 4 (7) The expiration date of the prescription;
- 5 (8) Full instructions on the use of the product in plain language; and
- 6 (9) The phrase "compounded per prescriber request" or a similar statement, either on the
- 7 prescription label or through the use of an auxiliary label attached to the prescription container.
- 8 (c) Upon request, a pharmacy shall provide a compounded drug to a practitioner for
- 9 administration to an individual patient. The compounded drug shall be for practitioner
- 10 administration only and shall not be redispensed. The pharmacy shall maintain records to indicate
- 11 what compounded drug products were provided to the practitioner.

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

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EXPLANATION
BY THE LEGISLATIVE COUNCIL
OF
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- 1 This act would set forth labeling requirements for a drug which is compounded at a
- 2 licensed pharmacy when used in a healthcare facility or physician's office.
- 3 This act would take effect upon passage.

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