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S.B. 246
1st Sub. (Green)

Senator Evan J. Vickers proposes the following substitute bill:

PHARMACY PRACTICE ACT AMENDMENTS

2017 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Evan J. Vickers

House Sponsor: _____

LONG TITLE

General Description:

This bill amends the Pharmacy Practice Act.

Highlighted Provisions:

This bill:

- requires certain Utah-licensed nonresident pharmacies to submit to an inspection as a prerequisite for licensure;
- excludes drugs administered under certain conditions from certain drug-container labeling requirements;
- permits certain pharmacists to administer long-acting injectable drugs intramuscularly under certain conditions; and
- makes technical changes.

Money Appropriated in this Bill:

None

Other Special Clauses:

None

Utah Code Sections Affected:

AMENDS:

58-17b-306, as last amended by Laws of Utah 2009, Chapter 183

58-17b-308, as last amended by Laws of Utah 2015, Chapter 258

58-17b-602, as last amended by Laws of Utah 2014, Chapter 72

ENACTS:

58-17b-625, Utah Code Annotated 1953

Be it enacted by the Legislature of the state of Utah:

Section 1. Section **58-17b-306** is amended to read:

58-17b-306. Qualifications for licensure as a pharmacy.

(1) Each applicant for licensure under this section, except for those applying for a class D license, shall:

(a) submit a written application in the form prescribed by the division;

(b) pay a fee as determined by the department under Section 63J-1-504;

(c) satisfy the division that the applicant, and each owner, officer, or manager of the applicant have not engaged in any act, practice, or omission, which when considered with the duties and responsibilities of a licensee under this section indicates there is cause to believe that issuing a license to the applicant is inconsistent with the interest of the public's health, safety, or welfare;

(d) demonstrate the licensee's operations will be in accordance with all federal, state, and local laws relating to the type of activity engaged in by the licensee, including regulations of the Federal Drug Enforcement Administration and Food and Drug Administration;

(e) maintain operating standards established by division rule made in collaboration with the board; and

(f) acknowledge the division's authority to inspect the licensee's business premises pursuant to Section 58-17b-103.

(2) Each applicant applying for a class D license shall:

(a) submit a written application in the form prescribed by the division;

(b) pay a fee as determined by the department under Section 63J-1-504;

(c) present to the division verification of licensure in the state where physically located and verification that such license is in good standing;

(d) provide a statement of the scope of pharmacy services that will be provided and a detailed description of the protocol as described by rule by which pharmacy care will be

provided, including any collaborative practice arrangements with other health care practitioners;

(e) sign an affidavit attesting that any healthcare practitioners employed by the applicant and physically located in Utah have the appropriate license issued by the division and in good standing; [~~and~~]

(f) sign an affidavit attesting that the applicant will abide by the pharmacy laws and regulations of the jurisdiction in which the pharmacy is located[~~.~~]; and

(g) if an applicant engages in compounding, submit the most recent inspection report:

(i) conducted within two years before the application for licensure; and

(ii) (A) conducted as part of the National Association of Boards of Pharmacy Verified Pharmacy Program; or

(B) performed by the state licensing agency of the state in which the applicant is a resident and in accordance with the National Association of Boards of Pharmacy multiple inspection blueprint program.

(3) Each license issued under this section shall be issued for a single, specific address, and is not transferable or assignable.

Section 2. Section **58-17b-308** is amended to read:

58-17b-308. Term of license -- Expiration -- Renewal.

(1) Except as provided in Subsection (2), each license issued under this chapter shall be issued in accordance with a two-year renewal cycle established by rule. A renewal period may be extended or shortened by as much as one year to maintain established renewal cycles or to change an established renewal cycle. Each license automatically expires on the expiration date shown on the license unless renewed by the licensee in accordance with Section 58-1-308.

(2) The duration of a pharmacy intern license may be no longer than:

(a) one year for a license issued under Subsection 58-17b-304(7)(b); or

(b) five years for a license issued under Subsection 58-17b-304(7)(a).

(3) A pharmacy intern license issued under this chapter may not be renewed, but may be extended by the division in collaboration with the board.

(4) As a prerequisite for renewal of a class D pharmacy license of a pharmacy that engages in compounding, a licensee shall submit the most recent inspection report:

(a) conducted within two years before the application for renewal; and

(b) (i) conducted as part of the National Association of Boards of Pharmacy Verified Pharmacy Program; or

(ii) performed by the state licensing agency of the state in which the applicant is a resident and in accordance with the National Association of Boards of Pharmacy multiple inspection blueprint program.

Section 3. Section **58-17b-602** is amended to read:

58-17b-602. Prescription orders -- Information required -- Alteration -- Labels -- Signatures -- Dispensing in pharmacies.

(1) Except as provided in Section 58-1-501.3, the minimum information that shall be included in a prescription order, and that may be defined by rule, is:

(a) the prescriber's name, address, and telephone number, and, if the order is for a controlled substance, the patient's age and the prescriber's DEA number;

(b) the patient's name and address or, in the case of an animal, the name of the owner and species of the animal;

(c) the date of issuance;

(d) the name of the medication or device prescribed and dispensing instructions, if necessary;

(e) the directions, if appropriate, for the use of the prescription by the patient or animal and any refill, special labeling, or other instructions;

(f) the prescriber's signature if the prescription order is written;

(g) if the order is an electronically transmitted prescription order, the prescribing practitioner's electronic signature; and

(h) if the order is a hard copy prescription order generated from electronic media, the prescribing practitioner's electronic or manual signature.

(2) The requirement of Subsection (1)(a) does not apply to prescription orders dispensed for inpatients by hospital pharmacies if the prescriber is a current member of the hospital staff and the prescription order is on file in the patient's medical record.

(3) Unless it is for a Schedule II controlled substance, a prescription order may be dispensed by a pharmacist or pharmacy intern upon an oral prescription of a practitioner only if the oral prescription is promptly reduced to writing.

(4) (a) Except as provided under Subsection (4)(b), a pharmacist or pharmacy intern

may not dispense or compound any prescription of a practitioner if the prescription shows evidence of alteration, erasure, or addition by any person other than the person writing the prescription.

(b) A pharmacist or pharmacy intern dispensing or compounding a prescription may alter or make additions to the prescription after receiving permission of the prescriber and may make entries or additions on the prescription required by law or necessitated in the compounding and dispensing procedures.

(5) (a) Each drug dispensed shall have a label securely affixed to the container indicating the following minimum information:

[~~(a)~~] (i) the name, address, and telephone number of the pharmacy;

[~~(b)~~] (ii) the serial number of the prescription as assigned by the dispensing pharmacy;

[~~(c)~~] (iii) the filling date of the prescription or its last dispensing date;

[~~(d)~~] (iv) the name of the patient, or in the case of an animal, the name of the owner and species of the animal;

[~~(e)~~] (v) the name of the prescriber;

[~~(f)~~] (vi) the directions for use and cautionary statements, if any, which are contained in the prescription order or are needed;

[~~(g)~~] (vii) except as provided in Subsection (7), the trade, generic, or chemical name, amount dispensed and the strength of dosage form, but if multiple ingredient products with established proprietary or nonproprietary names are prescribed, those products' names may be used; and

[~~(h)~~] (viii) the beyond use date.

(b) The requirements described in Subsections (5)(a)(i) through (vi) do not apply to a label on the container of a drug that a health care provider administers to a patient at:

(i) a pharmaceutical administration facility; or

(ii) a hospital licensed under Title 26, Chapter 21, Health Care Facility Licensing and Inspection Act.

(6) A hospital pharmacy that dispenses a prescription drug that is packaged in a multidose container to a hospital patient may provide the drug in the multidose container to the patient when the patient is discharged from the hospital if:

(a) the pharmacy receives a discharge order for the patient; and

(b) the pharmacy labels the drug with the:

(i) patient's name;

(ii) drug's name and strength;

(iii) directions for use of the drug, if applicable; and

(iv) pharmacy's name and phone number.

(7) If the prescriber specifically indicates the name of the prescription product should not appear on the label, then any of the trade, generic, chemical, established proprietary, and established nonproprietary names and the strength of dosage form may not be included.

(8) Prescribers are encouraged to include on prescription labels the information described in Section 58-17b-602.5 in accordance with the provisions of that section.

(9) A pharmacy may only deliver a prescription drug to a patient or a patient's agent:

(a) in person at the pharmacy; or

(b) via the United States Postal Service, a licensed common carrier, or supportive personnel, if the pharmacy takes reasonable precautions to ensure the prescription drug is:

(i) delivered to the patient or patient's agent; or

(ii) returned to the pharmacy.

Section 4. Section **58-17b-625** is enacted to read:

58-17b-625. Administration of a long-acting injectable drug therapy.

(1) A pharmacist may, in accordance with this section, administer a drug described in Subsection (2).

(2) Notwithstanding the provisions of Subsection 58-17b-102(57)(c)(ii)(B), the division shall make rules, in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, establishing training for a pharmacist to administer the following long-acting injectables intramuscularly:

(a) aripiprazole;

(b) paliperidone;

(c) risperidone;

(d) olanzapine;

(e) naltrexone;

(f) naloxone; and

(g) drugs approved and regulated by the United States Food and Drug Administration

for the treatment of the Human Immunodeficiency Virus.

(3) A pharmacist may not administer a drug listed under Subsection (2) unless the pharmacist:

(a) completes the training described in Subsection (2);

(b) administers the drug at a clinic or community pharmacy, as those terms are defined by the division, by administrative rule made in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act; and

(c) is directed by the Ŝ→ **[~~practitioner~~]** **physician, as that term is defined in Section 58-67-102 or Section 58-68-102,** ←Ŝ who issues the prescription to administer the drug.