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Representative {Rebecca D} Evan J. {Lockhart} Vickers proposes the following substitute bill:

PHARMACY PRACTICE ACT AMENDMENTS

2010 GENERAL SESSION STATE OF UTAH

Chief Sponsor: Curtis S. Bramble

House Sponsor: Rebecca D. Lockhart

LONG TITLE

General Description:

This bill amends the Pharmacy Practice Act.

Highlighted Provisions:

This bill:

- amends provisions related to exemptions from licensure;
- defines terms;
- exempts prescribing physicians from licensure under the Pharmacy Practice Act
 when a physician dispenses a cosmetic drug or {an }injectable weight loss drug to
 the physician's patient; and
- requires certain drug labeling and record keeping standards for the dispensing physician.

Monies Appropriated in this Bill:

None

Other Special Clauses:

None

Utah Code Sections Affected:

AMENDS:

58-17b-309, as last amended by Laws of Utah 2005, Chapter 71

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

Section 1. Section **58-17b-309** is amended to read:

58-17b-309. Exemptions from licensure.

- (1) For purposes of this section:
- (a) "Cosmetic drug":
- (i) means a prescription drug that is:
- (A) for the purpose of promoting attractiveness or altering the appearance of an individual; and
- (B) listed as a cosmetic drug subject to the exemption under this section by the division by administrative rule; and
 - (ii) does not include a prescription drug that is:
 - (A) a controlled substance;
 - (B) compounded by the {prescribing practitioner}physician; or
- (C) prescribed or used for the patient for the purpose of diagnosing, curing, mitigating, treating, or preventing a disease.
 - (b) "Injectable weight loss drug":
 - (i) means:
 - (\fix) \{\text{means}\}\) an injectable prescription drug prescribed to promote weight loss; and
- (B) listed as an injectable prescription drug subject to exemption under this section by the division by administrative rule; and
 - (ii) does not include:
 - (A) a prescription drug that is a controlled substance; or
 - (B) a drug compounded by the physician.
- (c) "Physician" means an individual licensed under either Chapter 67, Utah Medical Practice Act, or Chapter 68, Utah Osteopathic Medical Practice Act.
 - [(1)] (2) In addition to the exemptions from licensure in Section 58-1-307, the

following individuals may engage in the acts or practices described in this Subsection [(1)] (2) without being licensed under this chapter:

- (a) a person selling or providing contact lenses in accordance with Section 58-16a-801; [and]
- (b) an individual engaging in the practice of pharmacy technician under the direct personal supervision of a pharmacist while making satisfactory progress in an approved program as defined in division rule[:]; and
- (c) a physician who prescribes and dispenses a cosmetic drug or an injectable weight loss drug to the physician's patient in accordance with Subsection (4).
- [(2)] (3) In accordance with Subsection 58-1-303[(1)] (2)(a), an individual exempt under Subsection [(1)] (2)(b) must take all examinations as required by division rule following completion of an approved curriculum of education, within the required time frame. This exemption expires immediately upon notification of a failing score of an examination, and the individual may not continue working as a pharmacy technician even under direct supervision.
- (4) A physician is exempt from licensing under the provisions of Subsection (2)(c) if the physician:
 - (a) (i) writes a prescription for a cosmetic drug or {an }injectable weight loss drug; and (ii) informs the patient:
- (A) that the prescription may be filled at a pharmacy or dispensed in the physician's office;
 - (B) of the directions for appropriate use of the drug;
 - (C) of potential side-effects to the use of the drug; and
- (D) how to contact the physician if the patient has questions or concerns regarding the drug:
 - (b) dispenses a cosmetic drug or injectable weight loss drug :
 - (i) only to the physician's patients; and
 - ({ii) in a package labeled with:
- (A) the physician's name, address, and telephone number;
- (B) the date the drug is dispensed;
- (C) the patient's name;
- (D) the name and strength of the drug; and

- (E) directions for the drug's use, and any cautionary statements;
 - (c) enters into the patient's medical record:
 - (i) the name and strength of the drug dispensed; and
 - (ii) the date the drug was dispensed;
- (d) keeps the cosmetic drug or injectable weight loss drug in a locked cabinet or room, controls access to the cabinet or room, and maintains an ongoing inventory of the cabinet's or room's contents; and
- (e) when compounding an injectable weight loss drug, complies with state and federal laws that govern a pharmacy that compounds prescription drugs c) follows labeling, record keeping, patient counseling, and storage requirements established by administrative rule adopted by the division in consultation with the board.
- (5) (a) The division, in consultation with the board, shall adopt { an} administrative {rule}rules pursuant to Title 63G, Chapter 3, Utah Administrative Rulemaking Act to designate:
- (i) the prescription drugs that may be dispensed {as cosmetic drugs} under this section; and
 - (ii) the requirements under Subsection (4)(c).
- (b) When making a determination under Subsection (1)(a), the division and board shall consider any federal Food and Drug Administration indications or warnings associated with a drug when adopting a rule to designate a prescription drug that may be dispensed under this section.
- (tbc) The division may inspect the office of a physician who is dispensing under the provisions of this section, in order to determine whether the physician is in compliance with the provisions of this section. If a physician chooses to dispense under the provisions of this section, the physician consents to the jurisdiction of the division to inspect the physician's office and determine if the provisions of this section are being met by the physician.
- (teld) If a physician violates a provision of this section the physician may be subject to discipline under:
 - (i) this chapter; and
 - (ii) (A) Chapter 67, Utah Medical Practice Act; or
 - (B) Chapter 68, Utah Osteopathic Medical Practice Act.

(6) This section does not restrict or limit the scope of practice of an optometrist or optometric physician licensed under Chapter 16a, Utah Optometry Practice Act.