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EMPLOYER SPONSORED CLINIC - PRESCRIPTION DRUG AMENDMENTS

2014 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Stewart Barlow

Senate Sponsor: _____

LONG TITLE

General Description:

This bill amends the Pharmacy Practice Act to exempt a prescribing practitioner from its licensing requirements under certain circumstances.

Highlighted Provisions:

This bill:

- exempts a prescribing practitioner from the licensing requirements of the Pharmacy Practice Act if the prescribing practitioner dispenses a prepackaged drug at an employer sponsored clinic and complies with other requirements;
- repeals, subject to sunset review, the provisions of this bill relating to the exemption described above; and
- makes technical and conforming changes.

Money Appropriated in this Bill:

None

Other Special Clauses:

None

Utah Code Sections Affected:

AMENDS:

58-17b-301, as last amended by Laws of Utah 2013, Chapter 52

58-17b-302, as last amended by Laws of Utah 2013, Chapter 52

H.B. 106

58-17b-309, as last amended by Laws of Utah 2013, Chapter 278

58-17b-309.5, as enacted by Laws of Utah 2012, Chapter 234

63I-1-258, as last amended by Laws of Utah 2013, Chapters 55, 87, 222, 278, and 351

ENACTS:

58-17b-309.7, Utah Code Annotated 1953

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

Section 1. Section **58-17b-301** is amended to read:

58-17b-301. License required -- License classifications for individuals.

(1) A license is required to engage in the practice of pharmacy, telepharmacy, or the practice of a pharmacy technician, except as specifically provided in Section 58-1-307, 58-17b-309, [~~or~~] 58-17b-309.5, 58-17-309.6, or 58-17b-309.7.

(2) The division shall issue to an individual who qualifies under this chapter a license in the classification of:

(a) pharmacist;

(b) pharmacy intern; or

(c) pharmacy technician.

Section 2. Section **58-17b-302** is amended to read:

58-17b-302. License required -- License classifications for pharmacy facilities.

(1) A license is required to act as a pharmacy, except as specifically exempted from licensure under Section 58-1-307 [~~or~~], 58-17b-309, 58-17b-309.5, 58-17-309.6, or 58-17b-309.7.

(2) The division shall issue a pharmacy license to a facility that qualifies under this chapter in the classification of a:

(a) class A pharmacy;

(b) class B pharmacy;

(c) class C pharmacy;

(d) class D pharmacy; or

(e) class E pharmacy.

(3) Each place of business shall require a separate license. If multiple pharmacies exist at the same address, a separate license shall be required for each pharmacy.

(4) The division may further define or supplement the classifications of pharmacies. The division may impose restrictions upon classifications to protect the public health, safety, and welfare.

(5) Each pharmacy shall have a pharmacist-in-charge, except as otherwise provided by rule.

(6) Whenever an applicable statute or rule requires or prohibits action by a pharmacy, the pharmacist-in-charge and the owner of the pharmacy shall be responsible for all activities of the pharmacy, regardless of the form of the business organization.

Section 3. Section **58-17b-309** is amended to read:

58-17b-309. Exemptions from licensure.

(1) [~~For purposes of~~] As used in 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 or has been expressly approved for online dispensing, whether or not it is dispensed online or through a physician's office; and

(ii) does not include a prescription drug that is:

(A) a controlled substance;

(B) compounded by the physician; or

(C) prescribed or used for the patient for the purpose of diagnosing, curing, or preventing a disease.

(b) "Injectable weight loss drug":

(i) means an injectable prescription drug:

(A) 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 prescription drug that is a controlled substance.

(c) "Prescribing practitioner" means an individual licensed under:

(i) Chapter 31b, Nurse Practice Act, as an advanced practice registered nurse with

prescriptive practice;

(ii) Chapter 67, Utah Medical Practice Act;

(iii) Chapter 68, Utah Osteopathic Medical Practice Act; or

(iv) Chapter 70a, Physician Assistant Act.

(2) In addition to the exemptions from licensure in Sections 58-1-307 [~~and~~], 58-17b-309.5, 58-17b-309.6, and 58-17b-309.7, the following individuals may engage in the acts or practices described in this section without being licensed under this chapter:

(a) [~~if the~~] an individual [~~is~~] described in Subsections (2)(b), (d), or (e), if the individual notifies the division in writing of the individual's intent to dispense a drug under this [~~subsection~~] Subsection (2);

(b) a person selling or providing contact lenses in accordance with Section 58-16a-801;

(c) 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;

(d) a prescribing practitioner who prescribes and dispenses a cosmetic drug or an injectable weight loss drug to the prescribing practitioner's patient in accordance with Subsection (4); or

(e) an optometrist, as defined in Section 58-16a-102, acting within the optometrist's scope of practice as defined in Section 58-16a-601, who prescribes and dispenses a cosmetic drug to the optometrist's patient in accordance with Subsection (4).

(3) In accordance with Subsection 58-1-303(1)(a), an individual exempt under Subsection (2)(c) 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 prescribing practitioner or optometrist is exempt from licensing under the provisions of this part if the prescribing practitioner or optometrist:

(a) (i) writes a prescription for a drug the prescribing practitioner or optometrist has the authority to dispense under Subsection (4)(b); and

(ii) informs the patient:

(A) that the prescription may be filled at a pharmacy or dispensed in the prescribing

practitioner's or optometrist'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 prescribing practitioner or optometrist if the patient has questions or concerns regarding the drug;

(b) dispenses a cosmetic drug or injectable weight loss drug only to the prescribing practitioner's patients or for an optometrist, dispenses a cosmetic drug only to the optometrist's patients;

(c) follows labeling, record keeping, patient counseling, storage, purchasing and distribution, operating, treatment, and quality of care requirements established by administrative rule adopted by the division in consultation with the boards listed in Subsection (5)(a); and

(d) follows USP-NF 797 standards for sterile compounding if the drug dispensed to patients is reconstituted or compounded.

(5) (a) The division, in consultation with the board under this chapter and the relevant professional board, including the Physician Licensing Board, the Osteopathic Physician Licensing Board, the Physician Assistant Licensing Board, the Board of Nursing, the Optometrist Licensing Board, or the Online Prescribing, Dispensing, and Facilitation Board, shall adopt administrative rules pursuant to Title 63G, Chapter 3, Utah Administrative Rulemaking Act to designate:

(i) the prescription drugs that may be dispensed as a cosmetic drug or weight loss drug under this section; and

(ii) the requirements under Subsection (4)(c).

(b) When making a determination under Subsection (1)(a), the division and boards listed in Subsection (5)(a) may consider any federal Food and Drug Administration indications or approval associated with a drug when adopting a rule to designate a prescription drug that may be dispensed under this section.

(c) The division may inspect the office of a prescribing practitioner or optometrist who is dispensing under the provisions of this section, in order to determine whether the prescribing practitioner or optometrist is in compliance with the provisions of this section. If a prescribing practitioner or optometrist chooses to dispense under the provisions of this section, the

prescribing practitioner or optometrist consents to the jurisdiction of the division to inspect the prescribing practitioner's or optometrist's office and determine if the provisions of this section are being met by the prescribing practitioner or optometrist.

(d) If a prescribing practitioner or optometrist violates a provision of this section, the prescribing practitioner or optometrist may be subject to discipline under:

(i) this chapter; and

(ii) (A) Chapter 16a, Utah Optometry Practice Act;

(B) Chapter 31b, Nurse Practice Act;

(C) Chapter 67, Utah Medical Practice Act;

(D) Chapter 68, Utah Osteopathic Medical Practice Act;

(E) Chapter 70a, Physician Assistant Act; or

(F) Chapter 83, Online Prescribing, Dispensing, and Facilitation Licensing Act.

(6) Except as provided in Subsection (2)(e), 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.

Section 4. Section **58-17b-309.5** is amended to read:

58-17b-309.5. Exemption for prescribing practitioner of cancer drug regimen -- Division study of dispensing practitioners.

(1) [~~For purposes of~~] As used in this section, "cancer drug treatment regimen":

(a) means a prescription drug used to treat cancer, manage its symptoms, or provide continuity of care for a cancer patient;

(b) includes:

(i) a chemotherapy drug administered intravenously, orally, rectally, or by dermal methods; and

(ii) a drug used to support cancer treatment, including to treat, alleviate, or minimize physical and psychological symptoms or pain, or to improve patient tolerance of cancer treatments or prepare a patient for a subsequent course of therapy; and

(c) does not mean a drug listed under federal law as a Schedule I, II, or III drug.

(2) In addition to the [~~exemption~~] exemptions from licensure under [~~Section~~] Sections 58-1-307, 58-17b-309, 58-17b-309.6, and 58-17b-309.7, the following individuals are exempt from licensure under this chapter:

(a) an individual who:

(i) meets the requirements of Subsection (2)(b) or (c); and

(ii) notifies the division that the individual intends to dispense a cancer drug regimen under this section;

(b) a prescribing practitioner who:

(i) treats a patient who is currently undergoing chemotherapy in an outpatient clinic setting;

(ii) prescribes a cancer drug treatment regimen to the patient;

(iii) determines that providing the cancer drug treatment regimen to the patient in the outpatient clinic setting is in the best interest of the patient, or provides better access to care for the patient;

(iv) discloses to the patient that the cancer drug treatment regimen may be obtained from a pharmacy unaffiliated with the prescribing practitioner and offers to the patient the opportunity to consult with a pharmacist if the patient desires patient counseling;

(v) does not directly or indirectly mark up, charge a commission, or make a profit on providing the cancer drug regimen, but may obtain payment for expenses and services related to providing the cancer drug regimen;

(vi) provides the cancer drug treatment regimen to the patient, or directs another person under Subsection (2)(c) to provide the cancer drug treatment regimen to the patient;

(vii) is certified or eligible to be certified by the American Board of Internal Medicine in medical oncology;

(viii) reports to the Utah Controlled Substance Database in the same manner as required by Section 58-37f-203, and follows labeling, recordkeeping, patient counseling, purchasing and distribution, operating, treatment, quality of care, and storage requirements established by administrative rule adopted by the division in consultation with the board; and

(ix) follows the USP-NF 797 standards for sterile compounding if the drug dispensed to the patient is reconstituted or compounded; and

(c) a person who is not a prescribing practitioner who:

(i) is employed as a health care provider by a prescribing practitioner or the outpatient clinic setting in which the prescribing practitioner works and is acting within the individual's scope of practice;

(ii) is acting under the direction of a prescribing practitioner who is immediately available on site for any necessary consultation, and who has complied with Subsection (2)(b)(i);

(iii) prepares or provides the cancer drug treatment regimen to the patient at the outpatient clinic setting; and

(iv) follows Subsections (2)(b)(iv), (v), and (viii).

(3) (a) The division shall work with stakeholders to evaluate the exemptions to licensure under this title in Subsections 58-17b-309(2)(b), (d), and (e) and this section.

(b) The evaluation under this Subsection (3) shall include:

(i) practitioner compliance with the requirements of this section and Section 58-17b-309;

(ii) current research on dispensing and patient safety;

(iii) survey of other state dispensing laws; and

(iv) recommendations for future action concerning practitioner dispensing.

(c) The division shall report to the Legislature's Health and Human Services Interim Committee by November 30, 2012, and by November 30, 2013, with the results and recommendations from the evaluation required by this Subsection (3).

(4) This section sunsets in accordance with Section 63I-1-258.

Section 5. Section **58-17b-309.7** is enacted to read:

58-17b-309.7. Exemption for a practitioner prescribing prepackaged drugs at an employer sponsored clinic.

(1) As used in this section:

(a) "Employer sponsored clinic" means an entity that offers health care only to the employees of an exclusive group of employers and the employees' dependents.

(b) "Health care" is as defined in Section 31A-1-301.

(c) "Prepackaged drug" means a prescription drug that:

(i) is not listed under federal or state law as a Schedule I, II, III, IV, or V drug; and

(ii) is packaged in a fixed quantity per package by:

(A) the drug manufacturer;

(B) a pharmaceutical wholesaler or distributor; or

(C) a pharmacy licensed under this title.

(d) "Prescribing practitioner" is as defined in Section 58-17b-309.

(2) In addition to the exemptions described in Sections 58-1-307, 58-17b-309, 58-17b-309.5, and 58-17b-309.6, a prescribing practitioner is exempt from the licensing requirements of this chapter if the prescribing practitioner:

(a) treats an employee of one of an exclusive group of employers at an employer sponsored clinic;

(b) prescribes a prepackaged drug to the employee;

(c) dispenses the prepackaged drug at the employer sponsored clinic;

(d) notifies the division:

(i) that the prescribing practitioner intends to dispense the prepackaged drug at the employer sponsored clinic; and

(ii) of the drug the prescribing practitioner intends to dispense;

(e) determines that providing the prepackaged drug to the employee at the employer sponsored clinic is in the employee's best interest;

(f) informs the employee:

(i) that the employee may obtain the drug prescribed by the prescribing practitioner from a pharmacy that is unaffiliated with the prescribing practitioner;

(ii) of the directions for appropriate use of the prepackaged drug;

(iii) of potential side effects to the use of the prepackaged drug; and

(iv) how to contact the prescribing practitioner if the employee has questions or concerns regarding the drug;

(g) offers the employee the opportunity to consult with a pharmacist if the employee asks for patient counseling; and

(h) follows the administrative rules for a prescribing practitioner at an employer sponsored clinic established by the division under Subsection (4).

(3) If the chapter that governs the license of a prescribing practitioner dispensing a prepackaged drug under this section requires physician supervision in its scope of practice requirements, the prescribing practitioner shall only dispense a prepackaged drug under the supervision of an individual licensed under Chapter 67, Utah Medical Practice Act, or Chapter 68, Utah Osteopathic Medical Practice Act.

(4) The division shall, in consultation with the board of pharmacy and the Physicians

Licensing Board created in Section 58-67-201, adopt administrative rules pursuant to Title 63G, Chapter 3, Utah Administrative Rulemaking Act, that establish labeling, record keeping, patient counseling, purchasing and distribution, operating, treatment, quality of care, and storage requirements for a prescribing practitioner at an employer sponsored clinic.

(5) The division may inspect the office of a prescribing practitioner who is dispensing a prepackaged drug at an employer sponsored clinic to determine whether the prescribing practitioner is in compliance with this section.

(6) If a prescribing practitioner violates a provision of this section, the prescribing practitioner may be subject to discipline under:

(a) this chapter; and

(b) any other chapter that governs the terms of the prescribing practitioner's license.

(7) The division shall evaluate the exemption created by this section and report to the Legislature's Health and Human Services Interim Committee by July 1, 2016, and by July 1, 2018, on the results of the evaluation and the division's recommendations regarding the exemption.

Section 6. Section **63I-1-258** is amended to read:

63I-1-258. Repeal dates, Title 58.

(1) Title 58, Chapter 13, Health Care Providers Immunity from Liability Act, is repealed July 1, 2016.

(2) Title 58, Chapter 15, Health Facility Administrator Act, is repealed July 1, 2015.

(3) Section 58-17b-309.5 is repealed July 1, 2015.

(4) Section 58-17b-309.7 is repealed on July 1, 2018.

[~~(4)~~] (5) Title 58, Chapter 20a, Environmental Health Scientist Act, is repealed July 1, 2018.

[~~(5)~~] (6) Title 58, Chapter 40, Recreational Therapy Practice Act, is repealed July 1, 2023.

[~~(6)~~] (7) Title 58, Chapter 41, Speech-language Pathology and Audiology Licensing Act, is repealed July 1, 2019.

[~~(7)~~] (8) Title 58, Chapter 42a, Occupational Therapy Practice Act, is repealed July 1, 2015.

[~~(8)~~] (9) Title 58, Chapter 46a, Hearing Instrument Specialist Licensing Act, is

repealed July 1, 2023.

[~~(9)~~] (10) Title 58, Chapter 47b, Massage Therapy Practice Act, is repealed July 1, 2014.

[~~(10)~~] (11) Section 58-69-302.5 is repealed on July 1, 2015.

[~~(11)~~] (12) Title 58, Chapter 72, Acupuncture Licensing Act, is repealed July 1, 2017.

Legislative Review Note
as of 2-3-14 4:18 PM

Office of Legislative Research and General Counsel