

SB0161S04 compared with SB0161S03

~~deleted text~~ shows text that was in SB0161S03 but was deleted in SB0161S04.

inserted text shows text that was not in SB0161S03 but was inserted into SB0161S04.

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Senator Curtis S. Bramble proposes the following substitute bill:

PHARMACY PRACTICE ACT REVISIONS

2012 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Curtis S. Bramble

House Sponsor: ~~_____~~ Evan J. Vickers

LONG TITLE

General Description:

This bill amends the exemptions from licensure in the Pharmacy Practice Act.

Highlighted Provisions:

This bill:

- ▶ defines a cancer drug treatment regimen;
- ▶ exempts an oncologist from the licensing requirements under the Pharmacy Practice Act when the oncologist provides a cancer drug treatment regimen to a patient who is currently undergoing chemotherapy in an outpatient clinic;
- ▶ excludes Schedule I, II, and III drugs from the drugs an oncologist may provide to a patient under the licensing exemption from the Pharmacy Practice Act; and
- ▶ includes assistants to the oncologist who are under the supervision of the oncologist in the licensing exemption from the Pharmacy Practice Act.

SB0161S04 compared with SB0161S03

Money Appropriated in this Bill:

None

Other Special Clauses:

None

Utah Code Sections Affected:

AMENDS:

58-17b-309, as last amended by Laws of Utah 2011, Chapter 76

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) "~~+~~Cancer drug treatment regimen":

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

(ii) includes:

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

(B) 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

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

~~(a)~~ (b) "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 physician; or

SB0161S04 compared with SB0161S03

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

~~[(b)]~~ (c) "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.

~~[(e)]~~ (d) "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 Section 58-1-307, the following individuals may engage in the acts or practices described in this section without being licensed under this chapter:

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

(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;

(c) 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); ~~[and]~~

(d) 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)~~[-]; and~~

(e) (i) a prescribing practitioner who:

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

(B) prescribes a cancer drug treatment regimen to the patient:

SB0161S04 compared with SB0161S03

(C) 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;

(D) discloses to the patient that the cancer drug treatment regimen may be obtained from a pharmacy unaffiliated with the prescribing practitioner;

(E) 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;

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

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

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

(I) for drugs described in Subsection (1)(a)(ii)(B) only, follows the USP-NF 979 standards for sterile compounding if the drug dispensed to the patient is reconstituted or compounded; and

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

(A) is employed by a prescribing practitioner or the outpatient clinic setting in which the prescribing practitioner works;

(B) is acting under the direction of ~~the~~ a prescribing practitioner who is immediately available ~~as defined in 42C.F.R. 410.74(a)(2)(IV);~~ on site for any necessary consultation, and who has complied with Subsection (2)(e)(i);

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

(D) follows Subsections (2)(e)(i)(E) and (H).

(3) In accordance with Subsection 58-1-303(1)(a), an individual exempt under Subsection (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

SB0161S04 compared with SB0161S03

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; and

(c) follows labeling, record keeping, patient counseling, and storage requirements established by administrative rule adopted by the division in consultation with the boards listed in Subsection (5)(a).

(5) (a) The division, in consultation with the board under this chapter, the Physician Licensing Board, the Osteopathic Physician Licensing Board, the Physician Assistant Licensing Board, the Board of Nursing, and the Optometrist Licensing 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)~~(b), 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

SB0161S04 compared with SB0161S03

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

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