

## SB0161S06 compared with SB0161S05

~~{deleted text}~~ shows text that was in SB0161S05 but was deleted in SB0161S06.

inserted text shows text that was not in SB0161S05 but was inserted into SB0161S06.

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~~{Senator Curtis S}~~Representative Evan J. ~~{Bramble}~~Vickers 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

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#### LONG TITLE

##### General Description:

This bill amends the ~~{exemptions from licensure in}~~Pharmacy Practice Act to permit certain prescribing practitioners to dispense certain drugs without a license under the Pharmacy Practice Act, and makes conforming amendments in the Utah Optometry Practice Act, the Nurse Practice Act, the Utah Medical Practice Act, the Utah Osteopathic Medical Practice Act, and the Physician Assistant Act.

##### Highlighted Provisions:

This bill:

- ▶ ~~{defines a cancer drug treatment}~~requires a prescribing practitioner who will dispense a drug without being licensed under the Pharmacy Practice Act to notify the Division of Occupational and Professional Licensing of the practitioner's intent

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to dispense:

- ▶ requires the dispensing practitioner to follow purchasing and distribution requirements established by the division by administrative rule;
- ▶ defines cancer drug regimen;
- ▶ exempts an oncologist or medical personnel acting under the direction of an oncologist from ~~{the licensing requirements}~~ being licensed under the Pharmacy Practice Act ~~{when the oncologist provides}~~ to dispense a cancer drug ~~{treatment}~~ regimen to a patient who is ~~{currently}~~ undergoing chemotherapy in an outpatient clinic setting;
- ▶ excludes Schedule I, II, and III drugs from the drugs an oncologist may ~~{provide to a patient under the licensing exemption from}~~ dispense;
- ▶ makes it unprofessional conduct for a prescribing practitioner who dispenses a drug, to dispense the drug in violation of the exemption in 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}~~ directs the Division of Occupational and Professional Licensing to evaluate the prescribing practitioner exemptions from licensing for dispensing drugs and to report the findings of the evaluation to the Legislature; and
- ▶ sunsets the exemption from licensure for oncologists in July 2015.

### Money Appropriated in this Bill:

None

### Other Special Clauses:

None

### Utah Code Sections Affected:

AMENDS:

58-16a-502, as last amended by Laws of Utah 2000, Chapter 160

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

58-67-502, as last amended by Laws of Utah 2011, Chapter 206

58-68-502, as enacted by Laws of Utah 1996, Chapter 248

58-70a-502, as enacted by Laws of Utah 1997, Chapter 229

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63I-1-258, as last amended by Laws of Utah 2010, Chapter 188

### ENACTS:

58-17b-309.5, Utah Code Annotated 1953

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

Section 1. Section 58-16a-502 is amended to read:

#### **58-16a-502. Unprofessional conduct.**

"Unprofessional conduct" includes, in addition to the definition in Section 58-1-501:

(1) using or employing the services of an optometric assistant to assist a licensee in any manner not in accordance with:

- (a) the generally recognized practices and standards of ethics of the profession; or
- (b) applicable state law or division rule;

(2) failure to refer a patient to an appropriate licensed practitioner when:

- (a) the patient's condition does not respond to treatment; or
- (b) the treatment is not within the scope of competence or licensure of the licensee;

(3) providing confidential information regarding a patient to any third party who does not have a legal and professional ground for obtaining the information;

(4) knowingly prescribing, selling, giving away, or administering any prescription drug

[except unless:

(a) for a legitimate medical purpose [and];

(b) upon a proper diagnosis indicating the use of the drug in the amount prescribed or provided; and

(c) in compliance with Section 58-17b-309;

(5) giving or receiving directly or indirectly any fee, commission, rebate, or other compensation for professional services not actually and personally rendered, except as part of a legal relationship within a lawful professional partnership, corporation, or association;

(6) failure to transfer pertinent and necessary information from a patient's medical records to another optometrist or physician when so requested by the patient or his representative, as designated in writing; or

(7) failure to provide a contact lens prescription to a person who sells contact lenses in accordance with Section 58-16a-306.

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Section ~~{1}~~2. 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

(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.

~~{(c)}~~ ~~{(d)}~~ "Prescribing practitioner" means an individual licensed under:

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(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]~~ Sections 58-1-307 and 58-17b-309.5, the following individuals may engage in the acts or practices described in this section without being licensed under this chapter:

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

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

~~[(b)]~~ (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;

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

~~[(d)]~~ (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) ~~{[.]; 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;~~

~~———— (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;~~

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~~—— (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)(c)(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;~~

~~—— (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 as a healthcare 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;~~

~~—— (B) 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)(c)(i);~~

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

~~—— (D) follows Subsections (2)(c)(i)(E) and (H).~~

~~†~~

(3) In accordance with Subsection 58-1-303(1)(a), an individual exempt under Subsection (2)~~(b)~~(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

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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, 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, 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

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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)~~ (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 3. Section 58-17b-309.5 is enacted to read:

**58-17b-309.5. Exemption for prescribing practitioner of cancer drug regimen --**

**Division study of dispensing practitioners.**

(1) For purposes of 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 from licensure under Section 58-1-307, the following

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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

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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)(a), (c), and (d) 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 4. Section 58-67-502 is amended to read:

**58-67-502. Unprofessional conduct.**

"Unprofessional conduct" includes, in addition to the definition in Section 58-1-501[-]:

(1) using or employing the services of any individual to assist a licensee in any manner not in accordance with the generally recognized practices, standards, or ethics of the profession, state law, or division rule[-, or];

(2) making a material misrepresentation regarding the qualifications for licensure under Section 58-67-302.7[-]; or

(3) violating the dispensing requirements of Section 58-17b-309 or 58-17b-309.5 if applicable.

Section 5. Section 58-68-502 is amended to read:

**58-68-502. Unprofessional conduct.**

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"Unprofessional conduct" includes, in addition to the definition in Section 58-1-501[-]:

(1) using or employing the services of any individual to assist a licensee in any manner not in accordance with the generally recognized practices, standards, or ethics of the profession, state law, or division rule[-]; or

(2) violating the dispensing requirements of Section 58-17b-309 or 58-17b-309.5 if applicable.

Section 6. Section 58-70a-502 is amended to read:

### **58-70a-502. Unlawful conduct.**

"Unlawful conduct" includes:

(1) engaging in practice as a licensed physician assistant while not under the supervision of a supervising physician or substitute supervising physician[-]; or

(2) violating the drug dispensing requirements of Section 58-17b-309 or 58-17b-309.5, if applicable.

Section 7. Section 63I-1-258 is amended to read:

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

(1) Title 58, Chapter 9, Funeral Services Licensing Act, is repealed July 1, 2018.

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

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

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

~~(4)~~ (5) Title 58, Chapter 20a, Environmental Health Scientist Act, is repealed July 1, 2013.

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

2013.

~~(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, 2013.

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

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2014.

~~[(10)]~~ (11) Title 58, Chapter 72, Acupuncture Licensing Act, is repealed July 1, 2017.

~~[(11)]~~ (12) Section 58-13-2.5 is repealed July 1, 2013.