

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: _____

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 Pharmacy Practice Act when the oncologist provides a cancer drug treatment regime to a patient;
- ▶ excludes Schedule I, II, and III drugs from the drugs an oncologist may provide to a patient under the exemption from the Pharmacy Practice Act; and
- ▶ includes assistants to the oncologist who are under the general supervision of the oncologist in the exemption from the Pharmacy Practice Act.

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



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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 and 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

57 (ii) does not include a prescription drug that is a controlled substance.

58 [(~~e~~)] (d) "Prescribing practitioner" means an individual licensed under:

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

61 (ii) Chapter 67, Utah Medical Practice Act;

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

63 (iv) Chapter 70a, Physician Assistant Act.

64 (2) In addition to the exemptions from licensure in Section 58-1-307, the following
65 individuals may engage in the acts or practices described in this section without being licensed
66 under this chapter:

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

68 (b) an individual engaging in the practice of pharmacy technician under the direct
69 personal supervision of a pharmacist while making satisfactory progress in an approved
70 program as defined in division rule;

71 (c) a prescribing practitioner who prescribes and dispenses a cosmetic drug or an
72 injectable weight loss drug to the prescribing practitioner's patient in accordance with
73 Subsection (4); [~~and~~]

74 (d) an optometrist, as defined in Section 58-16a-102, acting within the optometrist's
75 scope of practice as defined in Section 58-16a-601, who prescribes and dispenses a cosmetic
76 drug to the optometrist's patient in accordance with Subsection (4)[~~;~~]; and

77 (e) (i) a prescribing practitioner who:

78 (A) treats a patient in an outpatient clinic setting;

79 (B) prescribes a cancer drug treatment regime to the patient;

80 (C) determines that providing the cancer drug treatment regime to the patient in the
81 outpatient clinic setting is in the best interest of the patient, or provides better access to care for
82 the patient;

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

85 (E) provides the cancer drug treatment regime to the patient, or directs another person
86 under Subsection (2)(e)(ii) to provide the cancer drug treatment regime to the patient;

87 (F) is certified or eligible to be certified by the American Board of Internal Medicine in

88 medical oncology; and

89 (G) follows labeling, recordkeeping, patient counseling, and storage requirements
90 established by administrative rule adopted by the division in consultation with the board; and

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

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

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

97 (C) provides the cancer drug treatment regime to the patient at the out patient clinic
98 setting; and

99 (D) follows Subsection (2)(e)(i)(G).

100 (3) In accordance with Subsection 58-1-303(1)(a), an individual exempt under
101 Subsection (2)(b) must take all examinations as required by division rule following completion
102 of an approved curriculum of education, within the required time frame. This exemption
103 expires immediately upon notification of a failing score of an examination, and the individual
104 may not continue working as a pharmacy technician even under direct supervision.

105 (4) A prescribing practitioner or optometrist is exempt from licensing under the
106 provisions of this part if the prescribing practitioner or optometrist:

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

109 (ii) informs the patient:

110 (A) that the prescription may be filled at a pharmacy or dispensed in the prescribing
111 practitioner's or optometrist's office;

112 (B) of the directions for appropriate use of the drug;

113 (C) of potential side-effects to the use of the drug; and

114 (D) how to contact the prescribing practitioner or optometrist if the patient has
115 questions or concerns regarding the drug;

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

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

122 (5) (a) The division, in consultation with the board under this chapter, the Physician
123 Licensing Board, the Osteopathic Physician Licensing Board, the Physician Assistant Licensing
124 Board, the Board of Nursing, and the Optometrist Licensing Board shall adopt administrative
125 rules pursuant to Title 63G, Chapter 3, Utah Administrative Rulemaking Act to designate:

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

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

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

133 (c) The division may inspect the office of a prescribing practitioner or optometrist who
134 is dispensing under the provisions of this section, in order to determine whether the prescribing
135 practitioner or optometrist is in compliance with the provisions of this section. If a prescribing
136 practitioner or optometrist chooses to dispense under the provisions of this section, the
137 prescribing practitioner or optometrist consents to the jurisdiction of the division to inspect the
138 prescribing practitioner's or optometrist's office and determine if the provisions of this section
139 are being met by the prescribing practitioner and optometrist.

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

142 (i) this chapter; and

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

144 (B) Chapter 31b, Nurse Practice Act;

145 (C) Chapter 67, Utah Medical Practice Act;

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

147 (E) Chapter 70a, Physician Assistant Act.

148 (6) Except as provided in Subsection (2)(d), this section does not restrict or limit the
149 scope of practice of an optometrist or optometric physician licensed under Chapter 16a, Utah

150 Optometry Practice Act.