

Representative Evan J. 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

LONG TITLE

General Description:

This bill amends the 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:

- ▶ 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 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 being licensed under the Pharmacy Practice Act to dispense a cancer drug regimen to a patient who is undergoing chemotherapy in an outpatient clinic setting;



- 26 ▶ excludes Schedule I, II, and III drugs from the drugs an oncologist may dispense;
- 27 ▶ makes it unprofessional conduct for a prescribing practitioner who dispenses a drug,
- 28 to dispense the drug in violation of the exemption in the Pharmacy Practice Act;
- 29 ▶ directs the Division of Occupational and Professional Licensing to evaluate the
- 30 prescribing practitioner exemptions from licensing for dispensing drugs and to
- 31 report the findings of the evaluation to the Legislature; and
- 32 ▶ sunsets the exemption from licensure for oncologists in July 2015.

33 **Money Appropriated in this Bill:**

34 None

35 **Other Special Clauses:**

36 None

37 **Utah Code Sections Affected:**

38 AMENDS:

39 **58-16a-502**, as last amended by Laws of Utah 2000, Chapter 160

40 **58-17b-309**, as last amended by Laws of Utah 2011, Chapter 76

41 **58-67-502**, as last amended by Laws of Utah 2011, Chapter 206

42 **58-68-502**, as enacted by Laws of Utah 1996, Chapter 248

43 **58-70a-502**, as enacted by Laws of Utah 1997, Chapter 229

44 **63I-1-258**, as last amended by Laws of Utah 2010, Chapter 188

45 ENACTS:

46 **58-17b-309.5**, Utah Code Annotated 1953



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

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

50 **58-16a-502. Unprofessional conduct.**

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

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

54 (a) the generally recognized practices and standards of ethics of the profession; or

55 (b) applicable state law or division rule;

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

- 57 (a) the patient's condition does not respond to treatment; or
- 58 (b) the treatment is not within the scope of competence or licensure of the licensee;
- 59 (3) providing confidential information regarding a patient to any third party who does
- 60 not have a legal and professional ground for obtaining the information;
- 61 (4) knowingly prescribing, selling, giving away, or administering any prescription drug
- 62 [~~except~~] unless:
- 63 (a) for a legitimate medical purpose [~~and~~];
- 64 (b) upon a proper diagnosis indicating the use of the drug in the amount prescribed or
- 65 provided; and
- 66 (c) in compliance with Section 58-17b-309;
- 67 (5) giving or receiving directly or indirectly any fee, commission, rebate, or other
- 68 compensation for professional services not actually and personally rendered, except as part of a
- 69 legal relationship within a lawful professional partnership, corporation, or association;
- 70 (6) failure to transfer pertinent and necessary information from a patient's medical
- 71 records to another optometrist or physician when so requested by the patient or his
- 72 representative, as designated in writing; or
- 73 (7) failure to provide a contact lens prescription to a person who sells contact lenses in
- 74 accordance with Section 58-16a-306.

75 Section 2. Section **58-17b-309** is amended to read:

76 **58-17b-309. Exemptions from licensure.**

- 77 (1) For purposes of this section:
- 78 (a) "Cosmetic drug":
- 79 (i) means a prescription drug that is:
- 80 (A) for the purpose of promoting attractiveness or altering the appearance of an
- 81 individual; and
- 82 (B) listed as a cosmetic drug subject to the exemption under this section by the division
- 83 by administrative rule; and
- 84 (ii) does not include a prescription drug that is:
- 85 (A) a controlled substance;
- 86 (B) compounded by the physician; or
- 87 (C) prescribed or used for the patient for the purpose of diagnosing, curing, mitigating,

88 treating, or preventing a disease.

89 (b) "Injectable weight loss drug":

90 (i) means an injectable prescription drug:

91 (A) prescribed to promote weight loss; and

92 (B) listed as an injectable prescription drug subject to exemption under this section by
93 the division by administrative rule; and

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

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

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

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

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

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

101 (2) In addition to the exemptions from licensure in [~~Section~~] Sections 58-1-307 and
102 58-17b-309.5, the following individuals may engage in the acts or practices described in this
103 section without being licensed under this chapter:

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

107 [~~(a)~~] (b) a person selling or providing contact lenses in accordance with Section
108 58-16a-801;

109 [~~(b)~~] (c) an individual engaging in the practice of pharmacy technician under the direct
110 personal supervision of a pharmacist while making satisfactory progress in an approved
111 program as defined in division rule;

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

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

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

119 Subsection (2)(~~(b)~~)(c) must take all examinations as required by division rule following
120 completion of an approved curriculum of education, within the required time frame. This
121 exemption expires immediately upon notification of a failing score of an examination, and the
122 individual may not continue working as a pharmacy technician even under direct supervision.

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

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

127 (ii) informs the patient:

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

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

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

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

134 (b) dispenses a cosmetic drug or injectable weight loss drug only to the prescribing
135 practitioner's patients or for an optometrist, dispenses a cosmetic drug only to the optometrist's
136 patients; [~~and~~]

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

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

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

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

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

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

154 (c) The division may inspect the office of a prescribing practitioner or optometrist who
155 is dispensing under the provisions of this section, in order to determine whether the prescribing
156 practitioner or optometrist is in compliance with the provisions of this section. If a prescribing
157 practitioner or optometrist chooses to dispense under the provisions of this section, the
158 prescribing practitioner or optometrist consents to the jurisdiction of the division to inspect the
159 prescribing practitioner's or optometrist's office and determine if the provisions of this section
160 are being met by the prescribing practitioner and optometrist.

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

- 163 (i) this chapter; and
- 164 (ii) (A) Chapter 16a, Utah Optometry Practice Act;
- 165 (B) Chapter 31b, Nurse Practice Act;
- 166 (C) Chapter 67, Utah Medical Practice Act;
- 167 (D) Chapter 68, Utah Osteopathic Medical Practice Act; or
- 168 (E) Chapter 70a, Physician Assistant Act.

169 (6) Except as provided in Subsection (2)~~(d)~~(e), this section does not restrict or limit
170 the scope of practice of an optometrist or optometric physician licensed under Chapter 16a,
171 Utah Optometry Practice Act.

172 Section 3. Section **58-17b-309.5** is enacted to read:

173 **58-17b-309.5. Exemption for prescribing practitioner of cancer drug regimen --**

174 **Division study of dispensing practitioners.**

175 (1) For purposes of this section, "cancer drug treatment regimen":

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

178 (b) includes:

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

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

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

185 (2) In addition to the exemption from licensure under Section 58-1-307, the following
186 individuals are exempt from licensure under this chapter:

187 (a) an individual who:

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

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

191 (b) a prescribing practitioner who:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

227 (i) practitioner compliance with the requirements of this section and Section
228 58-17b-309;

229 (ii) current research on dispensing and patient safety;

230 (iii) survey of other state dispensing laws; and

231 (iv) recommendations for future action concerning practitioner dispensing.

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

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

236 Section 4. Section **58-67-502** is amended to read:

237 **58-67-502. Unprofessional conduct.**

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

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

242 (2) making a material misrepresentation regarding the qualifications for licensure under

243 Section 58-67-302.7[-]; or

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

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

247 **58-68-502. Unprofessional conduct.**

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

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

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

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

255 **58-70a-502. Unlawful conduct.**

256 "Unlawful conduct" includes:

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

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

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

262 **63I-1-258. Repeal dates, Title 58.**

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

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

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

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

268 [~~(4)~~] (5) Title 58, Chapter 20a, Environmental Health Scientist Act, is repealed July 1,
269 2013.

270 [~~(5)~~] (6) Title 58, Chapter 40, Recreational Therapy Practice Act, is repealed July 1,
271 2013.

272 [~~(6)~~] (7) Title 58, Chapter 41, Speech-language Pathology and Audiology Licensing
273 Act, is repealed July 1, 2019.

274 [~~7~~] (8) Title 58, Chapter 42a, Occupational Therapy Practice Act, is repealed July 1,
275 2015.

276 [~~8~~] (9) Title 58, Chapter 46a, Hearing Instrument Specialist Licensing Act, is
277 repealed July 1, 2013.

278 [~~9~~] (10) Title 58, Chapter 47b, Massage Therapy Practice Act, is repealed July 1,
279 2014.

280 [~~10~~] (11) Title 58, Chapter 72, Acupuncture Licensing Act, is repealed July 1, 2017.

281 [~~11~~] (12) Section 58-13-2.5 is repealed July 1, 2013.