

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;

- ▶ excludes Schedule I, II, and III drugs from the drugs an oncologist may 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;

- ▶ directs the Division of Occupational and Professional Licensing to evaluate the

30 prescribing practitioner exemptions from licensing for dispensing drugs and to report the
31 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 **58-31b-502**, as last amended by Laws of Utah 2006, Chapter 291

42 **58-67-502**, as last amended by Laws of Utah 2011, Chapter 206

43 **58-68-502**, as enacted by Laws of Utah 1996, Chapter 248

44 **58-70a-502**, as enacted by Laws of Utah 1997, Chapter 229

45 **63I-1-258**, as last amended by Laws of Utah 2010, Chapter 188

46 ENACTS:

47 **58-17b-309.5**, Utah Code Annotated 1953



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

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

51 **58-16a-502. Unprofessional conduct.**

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

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

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

56 (b) applicable state law or division rule;

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

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

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

77 **58-17b-309. Exemptions from licensure.**

- 78 (1) For purposes of this section:
- 79 (a) "Cosmetic drug":
- 80 (i) means a prescription drug that is:
- 81 (A) for the purpose of promoting attractiveness or altering the appearance of an
- 82 individual; and
- 83 (B) listed as a cosmetic drug subject to the exemption under this section by the division
- 84 by administrative rule; and
- 85 (ii) does not include a prescription drug that is:

86 (A) a controlled substance;
87 (B) compounded by the physician; or
88 (C) prescribed or used for the patient for the purpose of diagnosing, curing, mitigating,
89 treating, or preventing a disease.

90 (b) "Injectable weight loss drug":

91 (i) means an injectable prescription drug:

92 (A) prescribed to promote weight loss; and

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

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

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

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

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

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

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

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

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

108 ~~[(a)]~~ (b) a person selling or providing contact lenses in accordance with Section
109 58-16a-801;

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

113 ~~[(c)]~~ (d) a prescribing practitioner who prescribes and dispenses a cosmetic drug or an

114 injectable weight loss drug to the prescribing practitioner's patient in accordance with
115 Subsection (4); ~~and~~ or
116 ~~(d)~~ (e) an optometrist, as defined in Section 58-16a-102, acting within the
117 optometrist's scope of practice as defined in Section 58-16a-601, who prescribes and dispenses
118 a cosmetic drug to the optometrist's patient in accordance with Subsection (4).

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

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

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

128 (ii) informs the patient:

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

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

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

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

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

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

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

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

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

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

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

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

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

164 (i) this chapter; and

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

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

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

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

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

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

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

174 **58-17b-309.5. Exemption for prescribing practitioner of cancer drug regimen --**
175 **Division study of dispensing practitioners.**

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

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

179 (b) includes:

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

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

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

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

188 (a) an individual who:

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

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

192 (b) a prescribing practitioner who:

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

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

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

198 the patient;

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

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

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

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

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

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

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

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

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

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

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

225 (3) (a) The division shall work with stakeholders to evaluate the exemptions to

226 licensure under this title in Subsections 58-17b-309(2)(b), (d), and (e) and this section.

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

228 (i) practitioner compliance with the requirements of this section and Section
229 58-17b-309;

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

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

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

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

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

237 Section 4. Section **58-31b-502** is amended to read:

238 **58-31b-502. Unprofessional conduct.**

239 "Unprofessional conduct" includes:

240 (1) failure to safeguard a patient's right to privacy as to the patient's person, condition,
241 diagnosis, personal effects, or any other matter about which the licensee is privileged to know
242 because of the licensee's or person with a certification's position or practice as a nurse or
243 practice as a medication aide certified;

244 (2) failure to provide nursing service or service as a medication aide certified in a
245 manner that demonstrates respect for the patient's human dignity and unique personal character
246 and needs without regard to the patient's race, religion, ethnic background, socioeconomic
247 status, age, sex, or the nature of the patient's health problem;

248 (3) engaging in sexual relations with a patient during any:

249 (a) period when a generally recognized professional relationship exists between the
250 person licensed or certified under this chapter and patient; or

251 (b) extended period when a patient has reasonable cause to believe a professional
252 relationship exists between the person licensed or certified under the provisions of this chapter
253 and the patient;

254 (4) (a) as a result of any circumstance under Subsection (3), exploiting or using
255 information about a patient or exploiting the licensee's or the person with a certification's
256 professional relationship between the licensee or holder of a certification under this chapter and
257 the patient; or

258 (b) exploiting the patient by use of the licensee's or person with a certification's
259 knowledge of the patient obtained while acting as a nurse or a medication aide certified;

260 (5) unlawfully obtaining, possessing, or using any prescription drug or illicit drug;

261 (6) unauthorized taking or personal use of nursing supplies from an employer;

262 (7) unauthorized taking or personal use of a patient's personal property;

263 (8) knowingly entering into any medical record any false or misleading information or
264 altering a medical record in any way for the purpose of concealing an act, omission, or record
265 of events, medical condition, or any other circumstance related to the patient and the medical or
266 nursing care provided;

267 (9) unlawful or inappropriate delegation of nursing care;

268 (10) failure to exercise appropriate supervision of persons providing patient care
269 services under supervision of the licensed nurse;

270 (11) employing or aiding and abetting the employment of an unqualified or unlicensed
271 person to practice as a nurse;

272 (12) failure to file or record any medical report as required by law, impeding or
273 obstructing the filing or recording of such a report, or inducing another to fail to file or record
274 such a report;

275 (13) breach of a statutory, common law, regulatory, or ethical requirement of
276 confidentiality with respect to a person who is a patient, unless ordered by a court;

277 (14) failure to pay a penalty imposed by the division;

278 (15) prescribing a schedule II-III controlled substance without a consulting physician or
279 outside of a consultation and referral plan; ~~and~~

280 (16) violating Section 58-31b-801[-]; and

281 (17) violating the dispensing requirements of Section 58-17b-309 or 58-17b-309.5, if

282 applicable.

283 Section 5. Section **58-67-502** is amended to read:

284 **58-67-502. Unprofessional conduct.**

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

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

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

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

293 Section 6. Section **58-68-502** is amended to read:

294 **58-68-502. Unprofessional conduct.**

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

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

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

301 Section 7. Section **58-70a-502** is amended to read:

302 **58-70a-502. Unlawful conduct.**

303 "Unlawful conduct" includes:

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

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

308 Section 8. Section **63I-1-258** is amended to read:

309 **63I-1-258. Repeal dates, Title 58.**

- 310 (1) Title 58, Chapter 9, Funeral Services Licensing Act, is repealed July 1, 2018.
- 311 (2) Title 58, Chapter 13, Health Care Providers Immunity from Liability Act, is
312 repealed July 1, 2016.
- 313 (3) Title 58, Chapter 15, Health Facility Administrator Act, is repealed July 1, 2015.
- 314 (4) Section 58-17b-309.5 is repealed July 1, 2015.
- 315 [~~(4)~~] (5) Title 58, Chapter 20a, Environmental Health Scientist Act, is repealed July 1,
316 2013.
- 317 [~~(5)~~] (6) Title 58, Chapter 40, Recreational Therapy Practice Act, is repealed July 1,
318 2013.
- 319 [~~(6)~~] (7) Title 58, Chapter 41, Speech-language Pathology and Audiology Licensing
320 Act, is repealed July 1, 2019.
- 321 [~~(7)~~] (8) Title 58, Chapter 42a, Occupational Therapy Practice Act, is repealed July 1,
322 2015.
- 323 [~~(8)~~] (9) Title 58, Chapter 46a, Hearing Instrument Specialist Licensing Act, is
324 repealed July 1, 2013.
- 325 [~~(9)~~] (10) Title 58, Chapter 47b, Massage Therapy Practice Act, is repealed July 1,
326 2014.
- 327 [~~(10)~~] (11) Title 58, Chapter 72, Acupuncture Licensing Act, is repealed July 1, 2017.
- 328 [~~(11)~~] (12) Section 58-13-2.5 is repealed July 1, 2013.