

1 **PHARMACY PRACTICE ACT AMENDMENTS**

2 2007 GENERAL SESSION

3 STATE OF UTAH

4 **Chief Sponsor: Peter C. Knudson**

5 House Sponsor: Scott L Wyatt

7 **LONG TITLE**

8 **General Description:**

9 This bill amends the Pharmacy Practice Act.

10 **Highlighted Provisions:**

11 This bill:

12 ▶ deletes archaic language related to the conversion of pharmacy licenses in existence
13 prior to July 1, 2004;

14 ▶ as a condition of licensure, requires a pharmacy intern who has received a degree
15 from a school or college of pharmacy accredited by the Accreditation Council on
16 Pharmacy Education to also have completed any intern hours required by division
17 rule;

18 ▶ extends the term of a pharmacy intern license held by a pharmacy student, resident,
19 or fellow from four years to five years;

20 ▶ amends the definition of "unprofessional conduct" as it relates to compensation for
21 patient referral;

22 ▶ amends the definition of "unprofessional conduct" as it relates to compensation for
23 acts in violation of the Pharmacy Practice Act;

24 ▶ adds violations of the Division of Occupational and Professional Licensing Act as a
25 basis for disciplinary action under the Pharmacy Practice Act;

26 ▶ specifies that prescription drugs must be dispensed at licensed pharmacies unless
27 they are delivered via the United States Postal Service, licensed common carrier, or



- 28 supportive personnel;
- 29 ▶ exempts class E pharmacies from the requirement that pharmacies be under the
- 30 supervision of a pharmacist-in-charge;
- 31 ▶ changes the deadline for the reporting of various matters by pharmacies to the
- 32 Division of Occupational and Professional Licensing;
- 33 ▶ makes clarifying changes; and
- 34 ▶ makes technical corrections.

35 Monies Appropriated in this Bill:

36 None

37 Other Special Clauses:

38 None

39 Utah Code Sections Affected:

40 AMENDS:

- 41 **58-17b-302**, as enacted by Chapter 280, Laws of Utah 2004
- 42 **58-17b-304**, as last amended by Chapter 160, Laws of Utah 2005
- 43 **58-17b-308**, as enacted by Chapter 280, Laws of Utah 2004
- 44 **58-17b-502**, as last amended by Chapter 160, Laws of Utah 2005
- 45 **58-17b-504**, as enacted by Chapter 280, Laws of Utah 2004
- 46 **58-17b-602**, as enacted by Chapter 280, Laws of Utah 2004
- 47 **58-17b-612**, as last amended by Chapter 160, Laws of Utah 2005
- 48 **58-17b-614**, as enacted by Chapter 280, Laws of Utah 2004

49

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

51 Section 1. Section **58-17b-302** is amended to read:

52 **58-17b-302. License classifications of pharmacy facilities.**

53 (1) A license is required to act as a pharmacy, except as specifically exempted from

54 licensure under Section 58-1-307.

55 (2) The division shall issue a pharmacy license to a facility that qualifies under this

56 chapter in the classification of a:

- 57 (a) class A pharmacy;
- 58 (b) class B pharmacy;

- 59 (c) class C pharmacy;
- 60 (d) class D pharmacy; or
- 61 (e) class E pharmacy.

62 (3) Each place of business shall require a separate license. If multiple pharmacies exist
 63 at the same address, a separate license shall be required for each pharmacy.

64 (4) The division may further define or supplement the classifications of pharmacies.
 65 The division may impose restrictions upon classifications to protect the public health, safety,
 66 and welfare.

67 (5) Each pharmacy shall have a pharmacist-in-charge, except as otherwise provided by
 68 rule.

69 (6) Whenever an applicable statute or rule requires or prohibits action by a pharmacy,
 70 the pharmacist-in-charge and the owner [~~or owners~~] of the pharmacy shall be responsible for all
 71 activities of the pharmacy, regardless of the form of the business organization.

72 [~~(7) Any facility holding a pharmacy license prior to July 1, 2004, shall be converted~~
 73 ~~from the classification of license currently held to the appropriate classification established~~
 74 ~~under this chapter upon their next renewal or reinstatement of licensure, in accordance with a~~
 75 ~~conversion schedule established by rule.]~~

76 Section 2. Section **58-17b-304** is amended to read:

77 **58-17b-304. Qualifications for licensure of pharmacy intern.**

78 Each applicant for licensure as a pharmacy intern shall:

- 79 (1) submit an application in a form prescribed by the division;
- 80 (2) pay a fee determined by the department under Section 63-38-3.2;
- 81 (3) produce satisfactory evidence of good moral character as it relates to the applicant's
 82 ability to practice pharmacy;
- 83 (4) complete a criminal background check and be free from criminal convictions as
 84 required by Section 58-17b-307, or as otherwise described in Section 58-1-501;
- 85 (5) have no physical or mental condition of a nature which prevents the applicant from
 86 engaging in the practice of pharmacy with reasonable skill, competency, and safety to the
 87 public;
- 88 (6) meet the preliminary educational qualifications required by division rule made in
 89 collaboration with the board; and

90 (7) meet one of the following educational criteria:

91 (a) be a current pharmacy student, a resident, or fellow in a program approved by
92 division rule made in collaboration with the board;

93 (b) have graduated and received a pharmacy degree from a school or college of
94 pharmacy which is accredited by the Accreditation Council on Pharmacy Education but not
95 completed the internship hours required by division rule for licensure as a pharmacist; or

96 (c) have graduated from a foreign pharmacy school and received certification of
97 equivalency from a credentialing agency approved by ~~the~~ division rule made in collaboration
98 with the board.

99 Section 3. Section **58-17b-308** is amended to read:

100 **58-17b-308. Term of license -- Expiration -- Renewal.**

101 (1) Except as provided in Subsection (2), each license issued under this chapter shall be
102 issued in accordance with a two-year renewal cycle established by rule. A renewal period may
103 be extended or shortened by as much as one year to maintain established renewal cycles or to
104 change an established renewal cycle. Each license automatically expires on the expiration date
105 shown on the license unless renewed by the licensee in accordance with Section 58-1-308.

106 (2) The duration of a pharmacy intern license may be no longer than:

107 (a) one year for a license issued under Subsection 58-17b-304(7)(b) or (c); or

108 (b) ~~four~~ five years for a license issued under Subsection 58-17b-304(7)(a).

109 (3) A pharmacy intern license issued under this chapter may not be renewed, but may
110 be extended by the division in collaboration with the board.

111 Section 4. Section **58-17b-502** is amended to read:

112 **58-17b-502. Unprofessional conduct.**

113 "Unprofessional conduct" includes:

114 (1) willfully deceiving or attempting to deceive the division, the board, or their agents
115 as to any relevant matter regarding compliance under this chapter;

116 (2) (a) ~~Ĥ→ [except for price discounts [conditional] based upon [volume purchases: (a)]~~
117 ~~purchase volumes paying rebates to practitioners or any other health care providers; and]~~

117a except as provided in Subsection (2)(b):

117b (i) paying or offering rebates to practitioners Ĥ→ or any other health care
117c providers, ←Ĥ or receiving Ĥ→ or soliciting ←Ĥ rebates from practitioners or
117c any other health care provider; or

117d (ii) paying, offering, Ĥ→ [or], ←Ĥ receiving Ĥ→, or soliciting ←Ĥ compensation in
117e1 the form of a commission, bonus,

117e rebate, kickback, or split fee arrangement with practitioners or any other health care
117f provider, for the purpose of obtaining referrals.

- 117g **(b) Subsection (2)(a) does not apply to:**
- 117h **(i) giving or receiving price discounts based on purchase volume;**
- 117i **(ii) passing along pharmaceutical manufacturer's rebates; or**
- 117j **(iii) ~~H→ [being compensated for] ←H providing H→ compensation for [dispensing,~~**
- 117k1 **billing and related] ←H services to a**
- 117k **veterinarian. ←H**
- 118 [~~(b) entering into any agreement with a medical practitioner or any other person for the~~
- 119 ~~payment or acceptance of compensation or its economic equivalent for recommending the~~
- 120 ~~professional services of either party;]~~

121 ~~Ĥ→ [(b)] ←Ĥ~~ ~~§→ [providing to or receiving from a physician, surgeon, organization,~~
 121a ~~agency, or other~~
 122 ~~person, either directly or indirectly, any form of compensation for the referral of a patient to a~~
 123 ~~pharmacy licensed under this chapter, including compensation in the form of a commission,~~
 124 ~~bonus, rebate, kickback, or split-fee arrangement;]~~ ~~Ĥ→ [for pharmacies and pharmacists not~~
 124a ~~participating in Medicare or Medicaid, an act that would violate the Federal Anti-kickback~~
 124b ~~Statute, 42 U.S.C. sec. 1320a-7b(b).]~~ ~~←§ ←Ĥ~~

125 (3) misbranding or adulteration of any drug or device or the sale, distribution, or
 126 dispensing of any outdated, misbranded, or adulterated drug or device;

127 (4) engaging in the sale or purchase of drugs or devices that are samples or packages
 128 bearing the inscription "sample" or "not for resale" or similar words or phrases;

129 (5) except as provided in Section 58-17b-503, accepting back and redistributing of any
 130 unused drug, or a part of it, after it has left the premises of any pharmacy, unless the drug is in
 131 a unit pack, as defined in Section 58-17b-503, or the manufacturer's sealed container, as
 132 defined in rule;

133 (6) ~~[being employed as]~~ an act in violation of this chapter committed by a person for
 134 any form of compensation if the act is incidental to the person's professional activities,
 135 including the activities of a pharmacist, pharmacy intern, or pharmacy technician~~[-or sharing~~
 136 ~~or receiving compensation in any form arising out of an act incidental to professional activities~~
 137 ~~in the course of which any person requires him to engage in any aspect of the practice of~~
 138 ~~pharmacy in violation of this chapter];~~

139 (7) violating Federal Title II, P.L. 91, Controlled Substances Act, ~~[or]~~ Title 58, Chapter
 140 37, Utah Controlled Substances Act, or rules ~~[and]~~ or regulations adopted under either act;

141 (8) requiring or permitting pharmacy interns or technicians to engage in activities
 142 outside the scope of practice for their respective license classifications, as defined in this
 143 chapter and division rules made in collaboration with the board, or beyond ~~[an individual's]~~
 144 their scope of training and ability;

145 (9) administering:

146 (a) without appropriate training, as defined by rule;

147 (b) without a physician's order, when one is required by law; and

148 (c) in conflict with a practitioner's written guidelines or written protocol for
 149 administering;

150 (10) disclosing confidential patient information in violation of the provisions of the
 151 Health Insurance Portability and Accountability Act of 1996 or other applicable law;

152 (11) engaging in the practice of pharmacy without a licensed pharmacist designated as
153 the pharmacist-in-charge;

154 (12) failing to report to the division any adverse action taken by another licensing
155 jurisdiction, government agency, law enforcement agency, or court for conduct that, in
156 substance would [~~constitute grounds for action, as defined in~~] be considered unprofessional
157 conduct under this section;

158 (13) [~~preparing~~] as a pharmacist or pharmacy intern, preparing a prescription drug for
159 sale to another pharmacist or pharmaceutical facility; and

160 (14) [~~preparing~~] as a pharmacist or pharmacy intern, preparing a prescription drug in a
161 dosage form which is regularly and commonly available from a manufacturer in quantities and
162 strengths prescribed by a practitioner.

163 Section 5. Section **58-17b-504** is amended to read:

164 **58-17b-504. Penalty for unlawful or unprofessional conduct -- Fines -- Citations.**

165 (1) Any person who violates any of the unlawful conduct [~~provision defined in~~]
166 provisions of Subsection 58-1-501(1)(a)(i) and Subsections 58-17b-501(7) and (11) is guilty of
167 a third degree felony.

168 (2) Any person who violates any of the unlawful conduct provisions [~~defined in~~] of
169 Subsection 58-1-501(1)(a)(ii), Subsections 58-1-501(1)(b) through (e), and Section
170 58-17b-501, except Subsections 58-17b-501(7) and (11), is guilty of a class A misdemeanor.

171 (3) (a) Subject to Subsection (5) and in accordance with Section 58-17b-401, for acts
172 of unprofessional or unlawful conduct, the division may:

173 (i) assess administrative penalties [~~in accordance with the provisions of Section~~
174 ~~58-17b-401 for acts of unprofessional or unlawful conduct or~~]; and

175 (ii) take any other appropriate administrative action [~~in accordance with the provisions~~
176 ~~of Section 58-17b-401~~].

177 (b) An administrative penalty imposed pursuant to this section shall be deposited in the
178 General Fund as a dedicated credit to be used by the division for pharmacy licensee education
179 and enforcement as provided in Section [~~58-12b-505~~] 58-17b-505.

180 (4) If a licensee has been convicted of violating Section 58-17b-501 prior to an
181 administrative finding of a violation of the same section, the licensee may not be assessed an
182 administrative fine under this chapter for the same offense for which the conviction was

183 obtained.

184 (5) (a) If upon inspection or investigation, the division concludes that a person has
185 violated the provisions of Section 58-17b-501[;] or 58-17b-502, [~~or~~] Chapter 37, Utah
186 Controlled Substances Act, Chapter 1, Division of Occupational and Professional Licensing
187 Act, or any rule or order issued with respect to these provisions, and that disciplinary action is
188 appropriate, the director or the director's designee from within the division shall promptly issue
189 a citation to the person according to this chapter and any pertinent rules, attempt to negotiate a
190 stipulated settlement, or notify the person to appear before an adjudicative proceeding
191 conducted under Title 63, Chapter 46b, Administrative Procedures Act.

192 (b) Any person who is in violation of the provisions of Section 58-17b-501[;] or
193 58-17b-502, [~~or~~] Chapter 37, Utah Controlled Substances Act, Chapter 1, Division of
194 Occupational and Professional Licensing Act, or any rule or order issued with respect to these
195 provisions, as evidenced by an uncontested citation, a stipulated settlement, or [~~by~~] a finding of
196 violation in an adjudicative proceeding, may be assessed a fine pursuant to this Subsection (5)
197 of up to \$10,000 per single violation or up to \$2,000 per day of ongoing violation, whichever is
198 greater, in accordance with a fine schedule established by rule, and may, in addition to or in
199 lieu of, be ordered to cease and desist from violating the provisions of Section 58-17b-501[;] or
200 58-17b-502, [~~or~~] Chapter 37, Utah Controlled Substances Act, Chapter 1, Division of
201 Occupational and Professional Licensing Act, or any rule or order issued with respect to these
202 provisions.

203 (c) Except for an administrative fine and a cease and desist order, the licensure
204 sanctions cited in Section 58-17b-401 may not be assessed through a citation.

205 (d) Each citation shall be in writing and specifically describe with particularity the
206 nature of the violation, including a reference to the provision of the chapter, rule, or order
207 alleged to have been violated. The citation shall clearly state that the recipient must notify the
208 division in writing within 20 calendar days of service of the citation [~~if the recipient wishes~~] in
209 order to contest the citation at a hearing conducted under Title 63, Chapter 46b, Administrative
210 Procedures Act. The citation shall clearly explain the consequences of failure to timely contest
211 the citation or to make payment of any fines assessed by the citation within the time specified
212 in the citation.

213 (e) Each citation issued under this section, or a copy of each citation, may be served

214 upon any person upon whom a summons may be served:

215 (i) in accordance with the Utah Rules of Civil Procedure;

216 (ii) personally or upon the person's agent by a division investigator or by any person
217 specially designated by the director; or

218 (iii) by mail.

219 (f) If within 20 calendar days from the service of a citation, the person to whom the
220 citation was issued fails to request a hearing to contest the citation, the citation becomes the
221 final order of the division and is not subject to further agency review. The period to contest the
222 citation may be extended by the division for cause.

223 (g) The division may refuse to issue or renew, suspend, revoke, or place on probation
224 the license of a licensee who fails to comply with the citation after it becomes final.

225 (h) The failure of an applicant for licensure to comply with a citation after it becomes
226 final is a ground for denial of license.

227 (i) No citation may be issued under this section after the expiration of six months
228 following the occurrence of any violation.

229 Section 6. Section **58-17b-602** is amended to read:

230 **58-17b-602. Prescription orders -- Information required -- Alteration -- Labels --**
231 **Signatures -- Dispensing in pharmacies.**

232 (1) The minimum information that shall be included in a prescription order, and that
233 may be defined by rule, is:

234 (a) the prescriber's name, address, and telephone number, and, if the order is for a
235 controlled substance, the patient's age and the prescriber's DEA number;

236 (b) the patient's name and address or, in the case of an animal, the name of the owner
237 and species of the animal;

238 (c) the date of issuance;

239 (d) the name of the medication or device prescribed and dispensing instructions, if
240 necessary;

241 (e) the directions, if appropriate, for the use of the prescription [~~if appropriate, for~~] by
242 the patient or animal[;] and any refill, special labeling, [~~and~~] or other instructions;

243 (f) the prescriber's signature if the prescription order is written;

244 (g) if the order is an electronically transmitted prescription order, the prescribing

245 practitioner's electronic signature; and

246 (h) if the order is a hard copy prescription order generated from electronic media, the
247 prescribing practitioner's electronic or manual signature.

248 (2) The requirement of Subsection (1)(a) does not apply to prescription orders
249 dispensed for inpatients by hospital pharmacies if the prescriber is a current member of the
250 hospital staff and the prescription order is on file in the patient's medical record.

251 (3) [~~The prescription order, except~~] Unless it is for a Schedule II controlled substance
252 [~~H~~], a prescription order may be dispensed by pharmacists or pharmacy interns upon an oral
253 prescription of a practitioner[;] only if the oral prescription is promptly reduced to writing.

254 (4) (a) [~~A~~] Except as provided under Subsection (4)(b), a pharmacist or pharmacy
255 intern may not dispense or compound any prescription of a practitioner if it shows evidence of
256 alteration, erasure, or addition by any person other than the person writing the prescription[;]
257 ~~except under Subsection (4)(b)~~].

258 (b) A pharmacist or pharmacy intern dispensing or compounding [~~the~~] a prescription
259 may alter or make additions to the prescription after receiving permission of the prescriber[~~, or~~]
260 and may make entries or additions on the prescription required by law or necessitated in the
261 compounding and dispensing procedures.

262 (5) Each drug dispensed shall have a label securely affixed to the container indicating
263 the following minimum information:

- 264 (a) the name, address, and telephone number of the pharmacy;
- 265 (b) the serial number of the prescription as assigned by the dispensing pharmacy;
- 266 (c) the filling date of the prescription or its last dispensing date;
- 267 (d) the name of the patient, or in the case of an animal, the name of the owner and
268 species of the animal;
- 269 (e) the name of the prescriber;
- 270 (f) the directions for use and cautionary statements, if any, which are contained in the
271 prescription order or are needed;

272 (g) except as provided in Subsection (6), the trade, generic, or chemical name, amount
273 dispensed and the strength of dosage form, but if multiple ingredient products with established
274 proprietary or nonproprietary names are prescribed, those products' names may be used; and

275 (h) the beyond use date.

276 (6) If the prescriber specifically indicates the name of the prescription product should
277 not appear on the label, then any of the trade, generic, [or] chemical [name and], established
278 proprietary, and established nonproprietary names and the strength of dosage form may not be
279 included.

280 (7) Except when it is delivered to the ultimate user via the United States Postal Service,
281 licensed common carrier, or supportive personnel, a prescription drug may be dispensed to the
282 ultimate user or his agent only at a licensed pharmacy.

283 Section 7. Section **58-17b-612** is amended to read:

284 **58-17b-612. Supervision -- Pharmacist-in-charge.**

285 (1) (a) Any pharmacy, except a wholesaler, distributor, [or] out-of-state mail service
286 pharmacy, or class E pharmacy, shall be under the general supervision of at least one
287 pharmacist licensed to practice in Utah. One pharmacist licensed in Utah shall be designated
288 as the pharmacist-in-charge, whose responsibility it is to oversee the operation of the pharmacy.

289 (b) Notwithstanding ~~[the provisions of]~~ Subsection 58-17b-102(64), a supervising
290 pharmacist does not have to be in the pharmacy or care facility but shall be available via a
291 telepharmacy system for immediate contact with the supervised pharmacy technician or
292 pharmacy intern if:

293 (i) the pharmacy is located in:

294 (A) a remote rural hospital, as defined in Section 26-21-13.6; or

295 (B) a clinic located in a remote rural county with less than 20 people per square mile;

296 (ii) the supervising pharmacist described in Subsection (1)(a) is not available; and

297 (iii) the telepharmacy system maintains records and files quarterly reports as required
298 by division rule to assure that patient safety is not compromised.

299 (2) Each out-of-state mail service pharmacy shall designate and identify to the division
300 a pharmacist holding a current license in good standing issued by the state in which the
301 pharmacy is located and who serves as the pharmacist-in-charge for all purposes under this
302 chapter.

303 Section 8. Section **58-17b-614** is amended to read:

304 **58-17b-614. Notification.**

305 (1) A pharmacy shall report in writing to the division not later than ten business days
306 ~~[after]~~ before the date of:

- 307 (a) a permanent closure of the pharmacy facility;
- 308 (b) a change of name or ownership of the pharmacy facility;
- 309 (c) a change of location of the pharmacy facility;
- 310 (d) a sale or transfer of any controlled substance as a result of the permanent closing or
- 311 change of ownership of the pharmacy facility;
- 312 (e) any matter or occurrence that the board requires by rule to be reported;
- 313 (f) a final administrative[;] disciplinary order against the pharmacy license holder by
- 314 the regulatory or licensing agency of the state in which the pharmacy is located if the pharmacy
- 315 is a class D pharmacy; or
- 316 (g) a final order against a pharmacist who is designated as the pharmacist-in-charge of
- 317 the pharmacy by the regulatory or licensing agency of the state in which the pharmacy is
- 318 located if the pharmacy is a class D pharmacy.
- 319 (2) A pharmacy shall report in writing to the division a disaster, accident, or emergency
- 320 that may [~~effect~~] affect the purity[;] or labeling of a drug, medication, device, or other material
- 321 used in the diagnosis or treatment of injury, illness, or disease immediately [~~on~~] upon the
- 322 occurrence of the disaster, accident, or emergency as defined by rule. [~~The~~]
- 323 (3) A reporting pharmacy shall maintain a copy of any notification required by this
- 324 section for two years and make a copy available for inspection.

Legislative Review Note
as of 1-19-07 5:05 PM

Office of Legislative Research and General Counsel

S.B. 160 - Pharmacy Practice Act Amendments

Fiscal Note

2007 General Session

State of Utah

State Impact

Enactment of this bill will not require additional appropriations.

Individual, Business and/or Local Impact

Enactment of this bill likely will not result in direct, measurable costs and/or benefits for businesses or local governments. Pharmacy students in the state could benefit as they would be allowed to be licensed earlier in their education and training.

1/29/2007, 10:50:26 AM, Lead Analyst: Eckersley, S.

Office of the Legislative Fiscal Analyst