PHARMACY PRACTICE ACT AMENDMENTS
2007 GENERAL SESSION
STATE OF UTAH
Chief Sponsor: Peter C. Knudson
House Sponsor: Scott L Wyatt
LONG TITLE
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General Description:
General Description: This bill amends the Pharmacy Practice Act.
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General Description:         This bill amends the Pharmacy Practice Act.         Highlighted Provisions:         This bill:         • deletes archaic language related to the conversion of pharmacy licenses in existence

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16 Pharmacy Education to also have completed any intern hours required by division

17 rule:

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- 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

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28	supportive personnel;
29	• exempts class E pharmacies from the requirement that pharmacies be under the
30	supervision of a pharmacist-in-charge;
31	<ul> <li>changes the deadline for the reporting of various matters by pharmacies to the</li> </ul>
32	Division of Occupational and Professional Licensing;
33	<ul> <li>makes clarifying changes; and</li> </ul>
34	<ul> <li>makes technical corrections.</li> </ul>
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
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50	Be it enacted by the Legislature of the state of Utah:
51	Section 1. Section <b>58-17b-302</b> 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 <b>58-17b-304</b> 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

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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 with the board. 98 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) except for price discounts [conditional] based upon [volume purchases: (a)] 117 purchase volumes paying rebates to practitioners or any other health care providers; and 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	(b) providing to or receiving from a physician, surgeon, organization, 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;
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;

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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 <u>any of</u> 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 <u>any of</u> the unlawful conduct provisions [defined in] <u>of</u>
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	<del>of Section 58-17b-401</del> ].
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

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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[;] <u>or</u>

193 58-17b-502, [or] Chapter 37, Utah Controlled Substances Act, <u>Chapter 1, Division of</u>

194 <u>Occupational and Professional Licensing Act</u>, 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[<del>,</del>] or

200 58-17b-502, [or] Chapter 37, Utah Controlled Substances Act, <u>Chapter 1, Division of</u>

201 <u>Occupational and Professional Licensing Act</u>, 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.

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

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214	upon any person <u>upon</u> 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 <b>58-17b-602</b> 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[ <del>, if appropriate, for</del> ] 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[,] <u>only</u> 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.

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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 <b>58-17b-612</b> 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 <b>58-17b-614</b> 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:

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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