

PHARMACY PRACTICE ACT AMENDMENTS

2011 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: David Clark

Senate Sponsor: _____

LONG TITLE

General Description:

This bill amends the Pharmacy Practice Act.

Highlighted Provisions:

This bill:

- ▶ provides definitions;
- ▶ clarifies the process as to when a therapeutic substitution may be substituted for a therapeutic prescription drug;
- ▶ requires the purchaser and the prescribing practitioner to authorize the substitution;
- ▶ requires out-of-state mail pharmacies to comply with the process established; and
- ▶ makes technical changes.

Money Appropriated in this Bill:

None

Other Special Clauses:

None

Utah Code Sections Affected:

AMENDS:

58-17b-102, as last amended by Laws of Utah 2010, Chapter 101

58-17b-607, as enacted by Laws of Utah 2004, Chapter 280

ENACTS:

58-17b-605.5, Utah Code Annotated 1953



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

Section 1. Section **58-17b-102** is amended to read:

58-17b-102. Definitions.

In addition to the definitions in Section 58-1-102, as used in this chapter:

(1) "Administering" means:

(a) the direct application of a prescription drug or device, whether by injection, inhalation, ingestion, or by any other means, to the body of a human patient or research subject by another person; or

(b) the placement by a veterinarian with the owner or caretaker of an animal or group of animals of a prescription drug for the purpose of injection, inhalation, ingestion, or any other means directed to the body of the animal by the owner or caretaker in accordance with written or verbal directions of the veterinarian.

(2) "Adulterated drug or device" means a drug or device considered adulterated under 21 U.S.C.S. Sec. 351 (2003).

(3) (a) "Analytical laboratory" means a facility in possession of prescription drugs for the purpose of analysis.

(b) "Analytical laboratory" does not include a laboratory possessing prescription drugs used as standards and controls in performing drug monitoring or drug screening analysis if the prescription drugs are prediluted in a human or animal body fluid, human or animal body fluid components, organic solvents, or inorganic buffers at a concentration not exceeding one milligram per milliliter when labeled or otherwise designated as being for in vitro diagnostic use.

(4) "Animal euthanasia agency" means an agency performing euthanasia on animals by the use of prescription drugs.

(5) "Automated pharmacy systems" includes mechanical systems which perform operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing, or distribution of medications, and which collect, control, and maintain all transaction information.

(6) "Beyond use date" means the date determined by a pharmacist and placed on a prescription label at the time of dispensing that indicates to the patient or caregiver a time

59 beyond which the contents of the prescription are not recommended to be used.

60 (7) "Branch pharmacy" means a pharmacy or other facility in a rural or medically
61 underserved area, used for the storage and dispensing of prescription drugs, which is dependent
62 upon, stocked by, and supervised by a pharmacist in another licensed pharmacy designated and
63 approved by the division as the parent pharmacy.

64 (8) "Board of pharmacy" or "board" means the Utah State Board of Pharmacy created
65 in Section 58-17b-201.

66 (9) "Centralized prescription processing" means the processing by a pharmacy of a
67 request from another pharmacy to fill or refill a prescription drug order or to perform
68 processing functions such as dispensing, drug utilization review, claims adjudication, refill
69 authorizations, and therapeutic interventions.

70 (10) "Class A pharmacy" means a pharmacy located in Utah that is authorized as a
71 retail pharmacy to compound or dispense a drug or dispense a device to the public under a
72 prescription order.

73 (11) "Class B pharmacy":

74 (a) means a pharmacy located in Utah:

75 (i) that is authorized to provide pharmaceutical care for patients in an institutional
76 setting; and

77 (ii) whose primary purpose is to provide a physical environment for patients to obtain
78 health care services; and

79 (b) (i) includes closed-door, hospital, clinic, nuclear, and branch pharmacies; and

80 (ii) pharmaceutical administration and sterile product preparation facilities.

81 (12) "Class C pharmacy" means a pharmacy located in Utah that is authorized to
82 engage in the manufacture, production, wholesale, or distribution of drugs or devices.

83 (13) "Class D pharmacy" means a nonresident pharmacy.

84 (14) "Class E pharmacy" means all other pharmacies.

85 (15) "Closed-door pharmacy" means a pharmacy that provides pharmaceutical care to a
86 defined and exclusive group of patients who have access to the services of the pharmacy
87 because they are treated by or have an affiliation with a specific entity, including a health
88 maintenance organization or an infusion company, but not including a hospital pharmacy, a
89 retailer of goods to the general public, or the office of a practitioner.

90 (16) "Collaborative pharmacy practice" means a practice of pharmacy whereby one or
91 more pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or
92 more practitioners under protocol whereby the pharmacist may perform certain pharmaceutical
93 care functions authorized by the practitioner or practitioners under certain specified conditions
94 or limitations.

95 (17) "Collaborative pharmacy practice agreement" means a written and signed
96 agreement between one or more pharmacists and one or more practitioners that provides for
97 collaborative pharmacy practice for the purpose of drug therapy management of patients and
98 prevention of disease of human subjects.

99 (18) (a) "Compounding" means the preparation, mixing, assembling, packaging, or
100 labeling of a limited quantity drug, sterile product, or device:

101 (i) as the result of a practitioner's prescription order or initiative based on the
102 practitioner, patient, or pharmacist relationship in the course of professional practice;

103 (ii) for the purpose of, or as an incident to, research, teaching, or chemical analysis and
104 not for sale or dispensing; or

105 (iii) in anticipation of prescription drug orders based on routine, regularly observed
106 prescribing patterns.

107 (b) "Compounding" does not include:

108 (i) the preparation of prescription drugs by a pharmacist or pharmacy intern for sale to
109 another pharmacist or pharmaceutical facility;

110 (ii) the preparation by a pharmacist or pharmacy intern of any prescription drug in a
111 dosage form which is regularly and commonly available from a manufacturer in quantities and
112 strengths prescribed by a practitioner; or

113 (iii) the preparation of a prescription drug, sterile product, or device which has been
114 withdrawn from the market for safety reasons.

115 (19) "Confidential information" has the same meaning as "protected health
116 information" under the Standards for Privacy of Individually Identifiable Health Information,
117 45 C.F.R. Parts 160 and 164.

118 (20) "Controlled substance" has the same definition as in Section 58-37-2.

119 (21) "Dietary supplement" has the same meaning as Public Law Title 103, Chapter
120 417, Sec. 3a(ff) which is incorporated by reference.

121 (22) "Dispense" means the interpretation, evaluation, and implementation of a
122 prescription drug order or device or nonprescription drug or device under a lawful order of a
123 practitioner in a suitable container appropriately labeled for subsequent administration to or use
124 by a patient, research subject, or an animal.

125 (23) "Distribute" means to deliver a drug or device other than by administering or
126 dispensing.

127 (24) (a) "Drug" means:

128 (i) a substance recognized in the official United States Pharmacopoeia, Official
129 Homeopathic Pharmacopoeia of the United States, or Official National Formulary, or any
130 supplement to any of them, intended for use in the diagnosis, cure, mitigation, treatment, or
131 prevention of disease in humans or animals;

132 (ii) a substance that is required by any applicable federal or state law or rule to be
133 dispensed by prescription only or is restricted to administration by practitioners only;

134 (iii) a substance other than food intended to affect the structure or any function of the
135 body of humans or other animals; and

136 (iv) substances intended for use as a component of any substance specified in
137 Subsections (24)(a)(i), (ii), and (iii)~~[, and (iv)]~~.

138 (b) "Drug" does not include dietary supplements.

139 (25) (a) "Drug product equivalent" means a drug product that is designated as the
140 therapeutic equivalent of another drug product in the Approved Drug Products with
141 Therapeutic Equivalence Evaluations prepared by the Center for Drug Evaluation and Research
142 of the Federal Food and Drug Administration.

143 (b) "Drug product equivalent" includes a generic form of a prescription drug that is
144 available in generic form and has an A rating in the United States Pharmacopeia and Drug
145 Index.

146 (26) "Drug regimen review" includes the following activities:

147 (a) evaluation of the prescription drug order and patient record for:

148 (i) known allergies;

149 (ii) rational therapy-contraindications;

150 (iii) reasonable dose and route of administration; and

151 (iv) reasonable directions for use;

152 (b) evaluation of the prescription drug order and patient record for duplication of
153 therapy;

154 (c) evaluation of the prescription drug order and patient record for the following
155 interactions:

156 (i) drug-drug;

157 (ii) drug-food;

158 (iii) drug-disease; and

159 (iv) adverse drug reactions; and

160 (d) evaluation of the prescription drug order and patient record for proper utilization,
161 including over- or under-utilization, and optimum therapeutic outcomes.

162 (27) "Drug sample" means a prescription drug packaged in small quantities consistent
163 with limited dosage therapy of the particular drug, which is marked "sample", is not intended to
164 be sold, and is intended to be provided to practitioners for the immediate needs of patients for
165 trial purposes or to provide the drug to the patient until a prescription can be filled by the
166 patient.

167 (28) "Electronic signature" means a trusted, verifiable, and secure electronic sound,
168 symbol, or process attached to or logically associated with a record and executed or adopted by
169 a person with the intent to sign the record.

170 (29) "Electronic transmission" means transmission of information in electronic form or
171 the transmission of the exact visual image of a document by way of electronic equipment.

172 (30) "Extern" means a college of pharmacy student enrolled in a college coordinated
173 practical experience program in a health care setting under the supervision of a preceptor, as
174 defined in this act, and approved by a college of pharmacy.

175 (31) "Hospital pharmacy" means a pharmacy providing pharmaceutical care to
176 inpatients of a general acute hospital or specialty hospital licensed by the Department of Health
177 under Title 26, Chapter 21, Health Care Facility Licensing and Inspection Act.

178 (32) "Legend drug" has the same meaning as prescription drug.

179 (33) "Licensed pharmacy technician" means an individual licensed with the division,
180 that may, under the supervision of a pharmacist, perform the activities involved in the
181 technician practice of pharmacy.

182 (34) "Manufacturer" means a person or business physically located in Utah licensed to

183 be engaged in the manufacturing of drugs or devices.

184 (35) (a) "Manufacturing" means:

185 (i) the production, preparation, propagation, conversion, or processing of a drug or
186 device, either directly or indirectly, by extraction from substances of natural origin or
187 independently by means of chemical or biological synthesis, or by a combination of extraction
188 and chemical synthesis, and includes any packaging or repackaging of the substance or labeling
189 or relabeling of its container; and

190 (ii) the promotion and marketing of such drugs or devices.

191 (b) "Manufacturing" includes the preparation and promotion of commercially available
192 products from bulk compounds for resale by pharmacies, practitioners, or other persons.

193 (c) "Manufacturing" does not include the preparation or compounding of a drug by a
194 pharmacist, pharmacy intern, or practitioner for that individual's own use or the preparation,
195 compounding, packaging, labeling of a drug, or incident to research, teaching, or chemical
196 analysis.

197 (36) "Medical order" means a lawful order of a practitioner which may include a
198 prescription drug order.

199 (37) "Medication profile" or "profile" means a record system maintained as to drugs or
200 devices prescribed for a pharmacy patient to enable a pharmacist or pharmacy intern to analyze
201 the profile to provide pharmaceutical care.

202 (38) "Misbranded drug or device" means a drug or device considered misbranded under
203 21 U.S.C.S. Sec. 352 (2003).

204 (39) (a) "Nonprescription drug" means a drug which:

205 (i) may be sold without a prescription; and

206 (ii) is labeled for use by the consumer in accordance with federal law.

207 (b) "Nonprescription drug" includes homeopathic remedies.

208 (40) "Nonresident pharmacy" means a pharmacy located outside of Utah that sells to a
209 person in Utah.

210 (41) "Nuclear pharmacy" means a pharmacy providing radio-pharmaceutical service.

211 (42) "Out-of-state mail service pharmacy" means a pharmaceutical facility located
212 outside the state that is licensed and in good standing in another state, that:

213 (a) ships, mails, or delivers by any lawful means a dispensed legend drug to a patient in

214 this state pursuant to a lawfully issued prescription;

215 (b) provides information to a patient in this state on drugs or devices which may
216 include, but is not limited to, advice relating to therapeutic values, potential hazards, and uses;
217 or

218 (c) counsels pharmacy patients residing in this state concerning adverse and therapeutic
219 effects of drugs.

220 (43) "Patient counseling" means the written and oral communication by the pharmacist
221 or pharmacy intern of information, to the patient or caregiver, in order to ensure proper use of
222 drugs, devices, and dietary supplements.

223 (44) "Pharmaceutical administration facility" means a facility, agency, or institution in
224 which:

225 (a) prescription drugs or devices are held, stored, or are otherwise under the control of
226 the facility or agency for administration to patients of that facility or agency;

227 (b) prescription drugs are dispensed to the facility or agency by a licensed pharmacist
228 or pharmacy intern with whom the facility has established a prescription drug supervising
229 relationship under which the pharmacist or pharmacy intern provides counseling to the facility
230 or agency staff as required, and oversees drug control, accounting, and destruction; and

231 (c) prescription drugs are professionally administered in accordance with the order of a
232 practitioner by an employee or agent of the facility or agency.

233 (45) (a) "Pharmaceutical care" means carrying out the following in collaboration with a
234 prescribing practitioner, and in accordance with division rule:

235 (i) designing, implementing, and monitoring a therapeutic drug plan intended to
236 achieve favorable outcomes related to a specific patient for the purpose of curing or preventing
237 the patient's disease;

238 (ii) eliminating or reducing a patient's symptoms; or

239 (iii) arresting or slowing a disease process.

240 (b) "Pharmaceutical care" does not include prescribing of drugs without consent of a
241 prescribing practitioner.

242 (46) "Pharmaceutical facility" means a business engaged in the dispensing, delivering,
243 distributing, manufacturing, or wholesaling of prescription drugs or devices within or into this
244 state.

245 (47) (a) "Pharmaceutical wholesaler or distributor" means a pharmaceutical facility
246 engaged in the business of wholesale vending or selling of any prescription drug or device to
247 other than the consumer or user of the prescription drug or device, which the pharmaceutical
248 facility has not produced, manufactured, compounded, or dispensed.

249 (b) "Pharmaceutical wholesaler or distributor" does not include a pharmaceutical
250 facility carrying out the following business activities:

251 (i) intracompany sales;

252 (ii) the sale, purchase, or trade of a prescription drug or device, or offer to sell,
253 purchase or trade a prescription drug or device between hospitals or other health care facilities
254 that are under common ownership or control of the management and operation of the facilities;

255 (iii) the sale, purchase, or trade of a prescription drug or device, or offer to sell,
256 purchase, or trade a prescription drug or device for emergency medical reasons, or to supply
257 another pharmaceutical facility to alleviate a temporary shortage; or

258 (iv) the distribution of a prescription drug or device as a sample by representatives of a
259 manufacturer.

260 (48) "Pharmacist" means an individual licensed by this state to engage in the practice
261 of pharmacy.

262 (49) "Pharmacist-in-charge" means a pharmacist currently licensed in good standing
263 who accepts responsibility for the operation of a pharmacy in conformance with all laws and
264 rules pertinent to the practice of pharmacy and the distribution of drugs, and who is personally
265 in full and actual charge of the pharmacy and all personnel.

266 (50) "Pharmacist preceptor" means a licensed pharmacist in good standing with two or
267 more years of licensed experience. The preceptor serves as a teacher, example of professional
268 conduct, and supervisor of interns in the professional practice of pharmacy.

269 (51) "Pharmacy" means any place where:

270 (a) drugs are dispensed;

271 (b) pharmaceutical care is provided;

272 (c) drugs are processed or handled for eventual use by a patient; or

273 (d) drugs are used for the purpose of analysis or research.

274 (52) "Pharmacy benefits manager or coordinator" means a person or entity that
275 administers the prescription drug or device portion of a health insurance plan on behalf of a

276 self-insured employer, insurance company, health maintenance organization, or other plan
277 sponsor, as defined by rule.

278 (53) "Pharmacy intern" means an individual licensed by this state to engage in practice
279 as a pharmacy intern.

280 (54) "Pharmacy technician training program" means an approved technician training
281 program providing education for pharmacy technicians.

282 (55) (a) "Practice as a licensed pharmacy technician" means engaging in practice as a
283 pharmacy technician under the general supervision of a licensed pharmacist and in accordance
284 with a scope of practice defined by division rule made in collaboration with the board.

285 (b) "Practice as a licensed pharmacy technician" does not include:

286 (i) performing a drug utilization review, prescription drug order clarification from a
287 prescriber, final review of the prescription and prescribed drug prepared for dispensing,
288 dispensing of the drug, or counseling a patient with respect to a prescription drug;

289 (ii) counseling regarding nonprescription drugs and dietary supplements unless
290 delegated by the supervising pharmacist; or

291 (iii) receiving new prescription drug orders when communicating telephonically or
292 electronically unless the original information is recorded so the pharmacist may review the
293 prescription drug order as transmitted.

294 (56) "Practice of pharmacy" includes the following:

295 (a) providing pharmaceutical care;

296 (b) collaborative pharmacy practice in accordance with a collaborative pharmacy
297 practice agreement;

298 (c) compounding, packaging, labeling, dispensing, administering, and the coincident
299 distribution of prescription drugs or devices, provided that the administration of a prescription
300 drug or device is:

301 (i) pursuant to a lawful order of a practitioner when one is required by law; and

302 (ii) in accordance with written guidelines or protocols:

303 (A) established by the licensed facility in which the prescription drug or device is to be
304 administered on an inpatient basis; or

305 (B) approved by the division, in collaboration with the board and the Physicians
306 Licensing Board, created in Section 58-67-201, if the prescription drug or device is to be

307 administered on an outpatient basis solely by a licensed pharmacist;

308 (d) participating in drug utilization review;

309 (e) ensuring proper and safe storage of drugs and devices;

310 (f) maintaining records of drugs and devices in accordance with state and federal law

311 and the standards and ethics of the profession;

312 (g) providing information on drugs or devices, which may include advice relating to
313 therapeutic values, potential hazards, and uses;

314 (h) providing drug product equivalents;

315 (i) supervising pharmacist's supportive personnel, pharmacy interns, and pharmacy
316 technicians;

317 (j) providing patient counseling, including adverse and therapeutic effects of drugs;

318 (k) providing emergency refills as defined by rule;

319 (l) telepharmacy; and

320 (m) formulary management intervention.

321 (57) "Practice of telepharmacy" means the practice of pharmacy through the use of
322 telecommunications and information technologies.

323 (58) "Practice of telepharmacy across state lines" means the practice of pharmacy
324 through the use of telecommunications and information technologies that occurs when the
325 patient is physically located within one jurisdiction and the pharmacist is located in another
326 jurisdiction.

327 (59) "Practitioner" means an individual currently licensed, registered, or otherwise
328 authorized by the appropriate jurisdiction to prescribe and administer drugs in the course of
329 professional practice.

330 (60) "Prescribe" means to issue a prescription:

331 (a) orally or in writing; or

332 (b) by telephone, facsimile transmission, computer, or other electronic means of
333 communication as defined by division rule.

334 (61) "Prescription" means an order issued:

335 (a) by a licensed practitioner in the course of that practitioner's professional practice or
336 by collaborative pharmacy practice agreement; and

337 (b) for a controlled substance or other prescription drug or device for use by a patient

338 or an animal.

339 (62) "Prescription device" means an instrument, apparatus, implement, machine,
340 contrivance, implant, in vitro reagent, or other similar or related article, and any component
341 part or accessory, which is required under federal or state law to be prescribed by a practitioner
342 and dispensed by or through a person or entity licensed under this chapter or exempt from
343 licensure under this chapter.

344 (63) "Prescription drug" means a drug that is required by federal or state law or rule to
345 be dispensed only by prescription or is restricted to administration only by practitioners.

346 (64) "Retail pharmacy" means a pharmaceutical facility dispensing prescription drugs
347 and devices to the general public.

348 (65) "Self-audit" means an internal evaluation of a pharmacy to determine compliance
349 with this chapter.

350 (66) "Supervising pharmacist" means a pharmacist who is overseeing the operation of
351 the pharmacy during a given day or shift.

352 (67) "Supportive personnel" means unlicensed individuals who:

353 (a) may assist a pharmacist, pharmacist preceptor, pharmacy intern, or licensed
354 pharmacy technician in nonjudgmental duties not included in the definition of the practice of
355 pharmacy, practice of a pharmacy intern, or practice of a licensed pharmacy technician, and as
356 those duties may be further defined by division rule adopted in collaboration with the board;
357 and

358 (b) are supervised by a pharmacist in accordance with rules adopted by the division in
359 collaboration with the board.

360 (68) "Unlawful conduct" is as defined in Sections 58-1-501 and 58-17b-501.

361 (69) "Unprofessional conduct" is as defined in Sections 58-1-501 and 58-17b-502 and
362 may be further defined by rule.

363 (70) "Veterinary pharmaceutical facility" means a pharmaceutical facility that
364 dispenses drugs intended for use by animals or for sale to veterinarians for the administration
365 for animals.

366 Section 2. Section **58-17b-605.5** is enacted to read:

367 **58-17b-605.5. Therapeutic substitutions.**

368 (1) For purposes of this section, "therapeutic substitution" means:

- 369 (a) a drug product that is chemically different than the drug originally prescribed; and
370 (b) does not include a drug product equivalent.
- 371 (2) A pharmacist or pharmacy intern dispensing a prescription order for a specific drug
372 by brand or proprietary name may dispense a therapeutic substitution for the prescribed drug
373 only if:
- 374 (a) the purchaser specifically requests or consents to the therapeutic substitution;
375 (b) the prescribing practitioner has provided express authorization, either in writing or
376 orally, for the therapeutic substitution to be dispensed;
- 377 (c) the therapeutic substitution is permitted to move in interstate commerce;
378 (d) the pharmacist or pharmacy intern:
- 379 (i) counsels the patient on:
- 380 (A) the use and the expected response to the therapeutic substitution; and
381 (B) the impact, if any, on the patient's out-of-pocket cost; and
- 382 (ii) indicates on the file copy of the prescription both the name of the prescribed drug
383 and the name of the therapeutic substitution dispensed in its place; and
- 384 (e) the therapeutic substitution is not otherwise prohibited by law.
- 385 (3) Each out-of-state mail service pharmacy dispensing into the state a therapeutic
386 substitution as a substitute for another drug shall comply with the requirements of this section,
387 including labeling and recordkeeping.
- 388 (4) A pharmacist or pharmacy intern who dispenses a prescription with a therapeutic
389 substitution under this section assumes no greater liability than would be incurred had the
390 pharmacist or pharmacy intern dispensed the prescription with the drug product prescribed.
- 391 (5) (a) If, in the opinion of the prescribing practitioner, it is in the best interest of the
392 patient that a therapeutic substitution not be dispensed for a prescribed drug, the practitioner
393 may indicate a prohibition on a therapeutic substitution either by writing "dispense as written"
394 or signing in the appropriate space where two lines have been preprinted on a prescription
395 order and captioned "dispense as written."
- 396 (b) If the prescription is communicated orally by the prescribing practitioner to the
397 pharmacist or pharmacy intern, the practitioner shall indicate the prohibition on therapeutic
398 substitution and that indication shall be noted in writing by the pharmacist or pharmacy intern
399 with the name of the practitioner and the words "orally by" and the initials of the pharmacist or

400 pharmacy intern written after it.

401 Section 3. Section **58-17b-607** is amended to read:

402 **58-17b-607. Drug substitution is not the practice of medicine -- Other causes of**
403 **action not denied.**

404 (1) The substitution of [~~any drug~~] a drug product equivalent as provided in Section
405 58-17b-605 or a therapeutic substitution as provided in Section 58-17b-605.5 by a licensed
406 pharmacist or pharmacy intern under this chapter does not constitute the practice of medicine.

407 (2) This chapter may not be construed to deny any individual a cause of action against
408 a pharmacist, pharmacy intern, or his employer for violations of this chapter, including failure
409 to observe accepted standards of care of the pharmaceutical profession.

Legislative Review Note
as of 2-8-11 2:28 PM

Office of Legislative Research and General Counsel