

1                                   **PHARMACY PRACTICE ACT MODIFICATIONS**

2   2012 GENERAL SESSION

3   STATE OF UTAH

4                                   **Chief Sponsor: Evan J. Vickers**

5   Senate Sponsor: Todd Weiler

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7   **LONG TITLE**

8   **General Description:**

9           This bill amends the Pharmacy Practice Act.

10 **Highlighted Provisions:**

11       This bill:

- 12           ▶ amends the definition of a pharmacy preceptor; and
- 13           ▶ amends provisions related to a prescribing practitioner providing sample drugs to a
- 14 patient.

15 **Money Appropriated in this Bill:**

16       None

17 **Other Special Clauses:**

18       None

19 **Utah Code Sections Affected:**

20 AMENDS:

21       **58-17b-102**, as last amended by Laws of Utah 2010, Chapter 101

22       **58-17b-610**, as enacted by Laws of Utah 2004, Chapter 280

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

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

26       **58-17b-102. Definitions.**

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

28       (1) "Administering" means:

29       (a) the direct application of a prescription drug or device, whether by injection,

30 inhalation, ingestion, or by any other means, to the body of a human patient or research subject  
31 by another person; or

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

36 (2) "Adulterated drug or device" means a drug or device considered adulterated under  
37 21 U.S.C.S. Sec. 351 (2003).

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

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

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

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

52 (6) "Beyond use date" means the date determined by a pharmacist and placed on a  
53 prescription label at the time of dispensing that indicates to the patient or caregiver a time  
54 beyond which the contents of the prescription are not recommended to be used.

55 (7) "Branch pharmacy" means a pharmacy or other facility in a rural or medically  
56 underserved area, used for the storage and dispensing of prescription drugs, which is dependent  
57 upon, stocked by, and supervised by a pharmacist in another licensed pharmacy designated and

58 approved by the division as the parent pharmacy.

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

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

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

68 (11) "Class B pharmacy":

69 (a) means a pharmacy located in Utah:

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

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

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

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

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

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

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

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

85 (16) "Collaborative pharmacy practice" means a practice of pharmacy whereby one or

86 more pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or  
87 more practitioners under protocol whereby the pharmacist may perform certain pharmaceutical  
88 care functions authorized by the practitioner or practitioners under certain specified conditions  
89 or limitations.

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

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

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

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

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

102 (b) "Compounding" does not include:

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

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

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

110 (19) "Confidential information" has the same meaning as "protected health  
111 information" under the Standards for Privacy of Individually Identifiable Health Information,  
112 45 C.F.R. Parts 160 and 164.

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

114 (21) "Dietary supplement" has the same meaning as Public Law Title 103, Chapter  
115 417, Sec. 3a(ff) which is incorporated by reference.

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

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

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

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

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

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

131 (iv) substances intended for use as a component of any substance specified in  
132 Subsections (24)(a)(i), (ii), (iii), and (iv).

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

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

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

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

140 (i) known allergies;

141 (ii) rational therapy-contraindications;

142 (iii) reasonable dose and route of administration; and  
143 (iv) reasonable directions for use;  
144 (b) evaluation of the prescription drug order and patient record for duplication of  
145 therapy;  
146 (c) evaluation of the prescription drug order and patient record for the following  
147 interactions:

148 (i) drug-drug;  
149 (ii) drug-food;  
150 (iii) drug-disease; and  
151 (iv) adverse drug reactions; and  
152 (d) evaluation of the prescription drug order and patient record for proper utilization,  
153 including over- or under-utilization, and optimum therapeutic outcomes.

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

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

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

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

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

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

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

174 (34) "Manufacturer" means a person or business physically located in Utah licensed to  
175 be engaged in the manufacturing of drugs or devices.

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

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

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

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

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

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

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

194 (38) "Misbranded drug or device" means a drug or device considered misbranded under  
195 21 U.S.C.S. Sec. 352 (2003).

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

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

- 198 (ii) is labeled for use by the consumer in accordance with federal law.
- 199 (b) "Nonprescription drug" includes homeopathic remedies.
- 200 (40) "Nonresident pharmacy" means a pharmacy located outside of Utah that sells to a  
201 person in Utah.
- 202 (41) "Nuclear pharmacy" means a pharmacy providing radio-pharmaceutical service.
- 203 (42) "Out-of-state mail service pharmacy" means a pharmaceutical facility located  
204 outside the state that is licensed and in good standing in another state, that:
- 205 (a) ships, mails, or delivers by any lawful means a dispensed legend drug to a patient in  
206 this state pursuant to a lawfully issued prescription;
- 207 (b) provides information to a patient in this state on drugs or devices which may  
208 include, but is not limited to, advice relating to therapeutic values, potential hazards, and uses;  
209 or
- 210 (c) counsels pharmacy patients residing in this state concerning adverse and therapeutic  
211 effects of drugs.
- 212 (43) "Patient counseling" means the written and oral communication by the pharmacist  
213 or pharmacy intern of information, to the patient or caregiver, in order to ensure proper use of  
214 drugs, devices, and dietary supplements.
- 215 (44) "Pharmaceutical administration facility" means a facility, agency, or institution in  
216 which:
- 217 (a) prescription drugs or devices are held, stored, or are otherwise under the control of  
218 the facility or agency for administration to patients of that facility or agency;
- 219 (b) prescription drugs are dispensed to the facility or agency by a licensed pharmacist  
220 or pharmacy intern with whom the facility has established a prescription drug supervising  
221 relationship under which the pharmacist or pharmacy intern provides counseling to the facility  
222 or agency staff as required, and oversees drug control, accounting, and destruction; and
- 223 (c) prescription drugs are professionally administered in accordance with the order of a  
224 practitioner by an employee or agent of the facility or agency.
- 225 (45) (a) "Pharmaceutical care" means carrying out the following in collaboration with a

226 prescribing practitioner, and in accordance with division rule:

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

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

231 (iii) arresting or slowing a disease process.

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

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

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

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

243 (i) intracompany sales;

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

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

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

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

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

258 (50) "Pharmacist preceptor" means a licensed pharmacist in good standing with [~~two~~  
259 one or more years of licensed experience. The preceptor serves as a teacher, example of  
260 professional conduct, and supervisor of interns in the professional practice of pharmacy.

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

262 (a) drugs are dispensed;

263 (b) pharmaceutical care is provided;

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

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

266 (52) "Pharmacy benefits manager or coordinator" means a person or entity that  
267 administers the prescription drug or device portion of a health insurance plan on behalf of a  
268 self-insured employer, insurance company, health maintenance organization, or other plan  
269 sponsor, as defined by rule.

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

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

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

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

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

281 (ii) counseling regarding nonprescription drugs and dietary supplements unless

282 delegated by the supervising pharmacist; or

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

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

287 (a) providing pharmaceutical care;

288 (b) collaborative pharmacy practice in accordance with a collaborative pharmacy  
289 practice agreement;

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

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

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

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

297 (B) approved by the division, in collaboration with the board and the Physicians  
298 Licensing Board, created in Section 58-67-201, if the prescription drug or device is to be  
299 administered on an outpatient basis solely by a licensed pharmacist;

300 (d) participating in drug utilization review;

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

302 (f) maintaining records of drugs and devices in accordance with state and federal law  
303 and the standards and ethics of the profession;

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

306 (h) providing drug product equivalents;

307 (i) supervising pharmacist's supportive personnel, pharmacy interns, and pharmacy  
308 technicians;

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

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

311 (l) telepharmacy; and

312 (m) formulary management intervention.

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

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

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

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

323 (a) orally or in writing; or

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

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

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

329 (b) for a controlled substance or other prescription drug or device for use by a patient  
330 or an animal.

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

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

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

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

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

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

345 (a) may assist a pharmacist, pharmacist preceptor, pharmacy intern, or licensed  
346 pharmacy technician in nonjudgmental duties not included in the definition of the practice of  
347 pharmacy, practice of a pharmacy intern, or practice of a licensed pharmacy technician, and as  
348 those duties may be further defined by division rule adopted in collaboration with the board;  
349 and

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

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

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

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

358 Section 2. Section **58-17b-610** is amended to read:

359 **58-17b-610. Patients' immediate needs -- Dispensing drug samples.**

360 (1) This chapter may not be construed to prevent the personal administration of drugs  
361 or medicines by practitioners licensed to prescribe in order to supply the immediate needs of  
362 ~~[their]~~ the practitioner's patients.

363 (2) Immediate need for a patient includes giving out drug samples ~~[for up to a~~  
364 ~~three-day supply or the amount necessary to determine the best pharmaceutical agent for that~~  
365 ~~specific patient.]~~ that:

- 366            (a) are not Schedule II drugs, opioids, or Benzodiazepines;  
367            (b) are prepackaged by the original manufacturer;  
368            (c) are provided to the prescribing practitioner free of charge and provided to the  
369 patient free of any direct or indirect charge;  
370            (d) do not exceed a 30-day supply for:  
371            (i) controlled substances; or  
372            (ii) non-controlled substances, unless a prescribing practitioner documents that  
373 providing more than a 30-day supply is medically necessary; and  
374            (e) (i) are marked on the immediate container to indicate that the drug is a sample; or  
375            (ii) are recorded in the patient's chart with the name and number of samples provided.  
376            (3) A prescribing practitioner who provides samples for a patient shall comply with  
377 Subsection (2).