

1                   **MAIL-ORDER WHOLESALE DRUG AMENDMENTS**

2                                   2014 GENERAL SESSION

3                                   STATE OF UTAH

4                           **Chief Sponsor: Stewart Barlow**

5                           Senate Sponsor: Evan J. Vickers

---

---

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 class C pharmacy subject to regulation under the  
13 Pharmacy Practice Act.

14 **Money Appropriated in this Bill:**

15       None

16 **Other Special Clauses:**

17       This bill takes effect on July 1, 2014.

18 **Utah Code Sections Affected:**

19 AMENDS:

20       **58-17b-102**, as last amended by Laws of Utah 2013, Chapters 52, 166, and 423

---

---

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

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

24       **58-17b-102. Definitions.**

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

26       (1) "Administering" means:

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

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

34 (2) "Adulterated drug or device" means a drug or device considered adulterated under  
35 21 U.S.C.S. Sec. 351 (2003).

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

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

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

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

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

53 (7) "Board of pharmacy" or "board" means the Utah State Board of Pharmacy created  
54 in Section [58-17b-201](#).

55 (8) "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 (9) "Centralized prescription processing" means the processing by a pharmacy of a  
60 request from another pharmacy to fill or refill a prescription drug order or to perform  
61 processing functions such as dispensing, drug utilization review, claims adjudication, refill  
62 authorizations, and therapeutic interventions.

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

66 (11) "Class B pharmacy":

67 (a) means a pharmacy located in Utah:

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

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

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

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

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

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

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

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

84 (16) "Collaborative pharmacy practice" means a practice of pharmacy whereby one or  
85 more pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or

86 more practitioners under protocol whereby the pharmacist may perform certain pharmaceutical  
87 care functions authorized by the practitioner or practitioners under certain specified conditions  
88 or limitations.

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

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

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

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

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

101 (b) "Compounding" does not include:

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

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

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

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

112 (20) "Controlled substance" has the same definition as in Section [58-37-2](#).

113 (21) "Dietary supplement" has the same meaning as Public Law Title 103, Chapter

114 417, Sec. 3a(ff) which is incorporated by reference.

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

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

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

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

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

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

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

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

133 (25) "Drug regimen review" includes the following activities:

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

135 (i) known allergies;

136 (ii) rational therapy-contraindications;

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

138 (iv) reasonable directions for use;

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

141 (c) evaluation of the prescription drug order and patient record for the following

142 interactions:

143 (i) drug-drug;

144 (ii) drug-food;

145 (iii) drug-disease; and

146 (iv) adverse drug reactions; and

147 (d) evaluation of the prescription drug order and patient record for proper utilization,

148 including over- or under-utilization, and optimum therapeutic outcomes.

149 (26) "Drug sample" means a prescription drug packaged in small quantities consistent  
150 with limited dosage therapy of the particular drug, which is marked "sample", is not intended to  
151 be sold, and is intended to be provided to practitioners for the immediate needs of patients for  
152 trial purposes or to provide the drug to the patient until a prescription can be filled by the  
153 patient.

154 (27) "Electronic signature" means a trusted, verifiable, and secure electronic sound,  
155 symbol, or process attached to or logically associated with a record and executed or adopted by  
156 a person with the intent to sign the record.

157 (28) "Electronic transmission" means transmission of information in electronic form or  
158 the transmission of the exact visual image of a document by way of electronic equipment.

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

162 (30) "Legend drug" has the same meaning as prescription drug.

163 (31) "Licensed pharmacy technician" means an individual licensed with the division,  
164 that may, under the supervision of a pharmacist, perform the activities involved in the  
165 technician practice of pharmacy.

166 (32) "Manufacturer" means a person or business physically located in Utah licensed to  
167 be engaged in the manufacturing of drugs or devices.

168 (33) (a) "Manufacturing" means:

169 (i) the production, preparation, propagation, conversion, or processing of a drug or

170 device, either directly or indirectly, by extraction from substances of natural origin or  
171 independently by means of chemical or biological synthesis, or by a combination of extraction  
172 and chemical synthesis, and includes any packaging or repackaging of the substance or labeling  
173 or relabeling of its container; and

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

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

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

181 (34) "Medical order" means a lawful order of a practitioner which may include a  
182 prescription drug order.

183 (35) "Medication profile" or "profile" means a record system maintained as to drugs or  
184 devices prescribed for a pharmacy patient to enable a pharmacist or pharmacy intern to analyze  
185 the profile to provide pharmaceutical care.

186 (36) "Misbranded drug or device" means a drug or device considered misbranded under  
187 21 U.S.C.S. Sec. 352 (2003).

188 (37) (a) "Nonprescription drug" means a drug which:

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

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

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

192 (38) "Nonresident pharmacy" means a pharmacy located outside of Utah that sells to a  
193 person in Utah.

194 (39) "Nuclear pharmacy" means a pharmacy providing radio-pharmaceutical service.

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

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

198 this state pursuant to a lawfully issued prescription;

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

201 or

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

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

207 (42) "Pharmaceutical administration facility" means a facility, agency, or institution in  
208 which:

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

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

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

217 (43) (a) "Pharmaceutical care" means carrying out the following in collaboration with a  
218 prescribing practitioner, and in accordance with division rule:

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

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

223 (iii) arresting or slowing a disease process.

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



226 (44) "Pharmaceutical facility" means a business engaged in the dispensing, delivering,  
227 distributing, manufacturing, or wholesaling of prescription drugs or devices within or into this  
228 state.

229 (45) (a) "Pharmaceutical wholesaler or distributor" means a pharmaceutical facility  
230 engaged in the business of wholesale vending or selling of a prescription drug or device to  
231 other than a consumer or user of the prescription drug or device that the pharmaceutical facility  
232 has not produced, manufactured, compounded, or dispensed.

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

235 (i) intracompany sales;

236 (ii) the sale, purchase, or trade of a prescription drug or device, or an offer to sell,  
237 purchase, or trade a prescription drug or device, if the activity is carried out between one or  
238 more of the following entities under common ownership or common administrative control, as  
239 defined by division rule:

240 (A) hospitals;

241 (B) pharmacies;

242 (C) chain pharmacy warehouses, as defined by division rule; or

243 (D) other health care entities, as defined by division rule;

244 (iii) the sale, purchase, or trade of a prescription drug or device, or an offer to sell,  
245 purchase, or trade a prescription drug or device, for emergency medical reasons, including  
246 supplying another pharmaceutical facility with a limited quantity of a drug, if:

247 (A) the facility is unable to obtain the drug through a normal distribution channel in  
248 sufficient time to eliminate the risk of harm to a patient that would result from a delay in  
249 obtaining the drug; and

250 (B) the quantity of the drug does not exceed an amount reasonably required for  
251 immediate dispensing to eliminate the risk of harm;

252 (iv) the distribution of a prescription drug or device as a sample by representatives of a  
253 manufacturer; and

254 (v) the distribution of prescription drugs, if:

255 (A) the dosage units distributed during a calendar year do not exceed five percent of  
256 the sum of the dosage units distributed by the facility during the calendar year and the dosage  
257 units dispensed by the facility during the calendar year; and

258 (B) the distribution otherwise complies with 21 C.F.R. Sec. 1307.11.

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

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

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

268 (49) "Pharmacy" means any place where:

269 (a) drugs are dispensed;

270 (b) pharmaceutical care is provided;

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

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

273 (50) "Pharmacy benefits manager or coordinator" means a person or entity that  
274 provides pharmacy benefit management services as defined in Section [49-20-502](#) on behalf of a  
275 self-insured employer, insurance company, health maintenance organization, or other plan  
276 sponsor, as defined by rule.

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

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

281 (53) (a) "Practice as a licensed pharmacy technician" means engaging in practice as a

282 pharmacy technician under the general supervision of a licensed pharmacist and in accordance  
283 with a scope of practice defined by division rule made in collaboration with the board.

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

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

288 (ii) except as permitted by rules made by the division in consultation with the board,  
289 final review of a prescribed drug prepared for dispensing;

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

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

295 (54) "Practice of pharmacy" includes the following:

296 (a) providing pharmaceutical care;

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

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

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

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

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

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

309 (d) participating in drug utilization review;

- 310 (e) ensuring proper and safe storage of drugs and devices;
- 311 (f) maintaining records of drugs and devices in accordance with state and federal law
- 312 and the standards and ethics of the profession;
- 313 (g) providing information on drugs or devices, which may include advice relating to
- 314 therapeutic values, potential hazards, and uses;
- 315 (h) providing drug product equivalents;
- 316 (i) supervising pharmacist's supportive personnel, pharmacy interns, and pharmacy
- 317 technicians;
- 318 (j) providing patient counseling, including adverse and therapeutic effects of drugs;
- 319 (k) providing emergency refills as defined by rule;
- 320 (l) telepharmacy; and
- 321 (m) formulary management intervention.

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

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

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

331 (58) "Prescribe" means to issue a prescription:

- 332 (a) orally or in writing; or
- 333 (b) by telephone, facsimile transmission, computer, or other electronic means of
- 334 communication as defined by division rule.

335 (59) "Prescription" means an order issued:

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

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

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

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

347 (62) "Research using pharmaceuticals" means research:

348 (a) conducted in a research facility, as defined by division rule, that is associated with a  
349 university or college in the state accredited by the Northwest Commission on Colleges and  
350 Universities;

351 (b) requiring the use of a controlled substance, prescription drug, or prescription  
352 device;

353 (c) that uses the controlled substance, prescription drug, or prescription device in  
354 accordance with standard research protocols and techniques, including, if required, those  
355 approved by an institutional review committee; and

356 (d) that includes any documentation required for the conduct of the research and the  
357 handling of the controlled substance, prescription drug, or prescription device.

358 (63) "Retail pharmacy" means a pharmaceutical facility dispensing prescription drugs  
359 and devices to the general public.

360 (64) "Self-audit" means an internal evaluation of a pharmacy to determine compliance  
361 with this chapter.

362 (65) "Supervising pharmacist" means a pharmacist who is overseeing the operation of  
363 the pharmacy during a given day or shift.

364 (66) "Supportive personnel" means unlicensed individuals who:

365 (a) may assist a pharmacist, pharmacist preceptor, pharmacy intern, or licensed

366 pharmacy technician in nonjudgmental duties not included in the definition of the practice of  
367 pharmacy, practice of a pharmacy intern, or practice of a licensed pharmacy technician, and as  
368 those duties may be further defined by division rule adopted in collaboration with the board;  
369 and

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

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

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

375 (69) "Veterinary pharmaceutical facility" means a pharmaceutical facility that  
376 dispenses drugs intended for use by animals or for sale to veterinarians for the administration  
377 for animals.

378 Section 2. **Effective date.**

379 This bill takes effect on July 1, 2014.