

Senator Evan J. Vickers proposes the following substitute bill:

PHARMACY PRACTICE ACT AMENDMENTS

2013 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Evan J. Vickers

House Sponsor: Dean Sanpei

LONG TITLE

General Description:

This bill amends the Pharmacy Practice Act.

Highlighted Provisions:

This bill:

- ▶ deletes "extern" from Pharmacy Practice Act definitions;
- ▶ amends the definition of "pharmaceutical wholesaler or distributor";
- ▶ amends the definition of "practice as a licensed pharmacy technician";
- ▶ amends pharmacy intern licensure qualifications;
- ▶ amends pharmacy technician licensure qualifications;
- ▶ authorizes, under certain circumstances, the dispensing of one or more refills at the time a legend drug prescription is dispensed;
- ▶ clarifies that funds paid for certain refills dispensed at the time a prescription is dispensed may not be recouped as the result of a pharmacy audit;
- ▶ makes conforming amendments; and
- ▶ makes technical changes.

Money Appropriated in this Bill:

None

Other Special Clauses:



26 None

27 **Utah Code Sections Affected:**

28 AMENDS:

29 **58-17b-102**, as last amended by Laws of Utah 2012, Chapters 265 and 320

30 **58-17b-304**, as last amended by Laws of Utah 2012, Chapter 93

31 **58-17b-305**, as last amended by Laws of Utah 2012, Chapter 93

32 **58-17b-612**, as last amended by Laws of Utah 2010, Chapter 101

33 **58-17b-622**, as enacted by Laws of Utah 2012, Chapter 265

34 ENACTS:

35 **58-17b-608.1**, Utah Code Annotated 1953



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

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

39 **58-17b-102. Definitions.**

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

41 (1) "Administering" means:

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

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

49 (2) "Adulterated drug or device" means a drug or device considered adulterated under
50 21 U.S.C.S. Sec. 351 (2003).

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

53 (b) "Analytical laboratory" does not include a laboratory possessing prescription drugs
54 used as standards and controls in performing drug monitoring or drug screening analysis if the
55 prescription drugs are prediluted in a human or animal body fluid, human or animal body fluid
56 components, organic solvents, or inorganic buffers at a concentration not exceeding one

57 milligram per milliliter when labeled or otherwise designated as being for in vitro diagnostic
58 use.

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

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

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

68 (7) "Board of pharmacy" or "board" means the Utah State Board of Pharmacy created
69 in Section 58-17b-201.

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

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

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

81 (11) "Class B pharmacy":

82 (a) means a pharmacy located in Utah:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

115 (b) "Compounding" does not include:

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

118 (ii) the preparation by a pharmacist or pharmacy intern of any prescription drug in a

119 dosage form which is regularly and commonly available from a manufacturer in quantities and
120 strengths prescribed by a practitioner; or

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

123 (19) "Confidential information" has the same meaning as "protected health
124 information" under the Standards for Privacy of Individually Identifiable Health Information,
125 45 C.F.R. Parts 160 and 164.

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

127 (21) "Dietary supplement" has the same meaning as Public Law Title 103, Chapter
128 417, Sec. 3a(ff) which is incorporated by reference.

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

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

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

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

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

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

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

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

147 (25) "Drug product equivalent" means a drug product that is designated as the
148 therapeutic equivalent of another drug product in the Approved Drug Products with
149 Therapeutic Equivalence Evaluations prepared by the Center for Drug Evaluation and Research

150 of the Federal Food and Drug Administration.

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

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

153 (i) known allergies;

154 (ii) rational therapy-contraindications;

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

156 (iv) reasonable directions for use;

157 (b) evaluation of the prescription drug order and patient record for duplication of

158 therapy;

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

160 interactions:

161 (i) drug-drug;

162 (ii) drug-food;

163 (iii) drug-disease; and

164 (iv) adverse drug reactions; and

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

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

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

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

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

177 [~~(30) "Extern" means a college of pharmacy student enrolled in a college coordinated
178 practical experience program in a health care setting under the supervision of a preceptor, as
179 defined in this act, and approved by a college of pharmacy.]~~

180 [~~(31)~~ (30) "Hospital pharmacy" means a pharmacy providing pharmaceutical care to

181 inpatients of a general acute hospital or specialty hospital licensed by the Department of Health
182 under Title 26, Chapter 21, Health Care Facility Licensing and Inspection Act.

183 ~~[(32)]~~ (31) "Legend drug" has the same meaning as prescription drug.

184 ~~[(33)]~~ (32) "Licensed pharmacy technician" means an individual licensed with the
185 division, that may, under the supervision of a pharmacist, perform the activities involved in the
186 technician practice of pharmacy.

187 ~~[(34)]~~ (33) "Manufacturer" means a person or business physically located in Utah
188 licensed to be engaged in the manufacturing of drugs or devices.

189 ~~[(35)]~~ (34) (a) "Manufacturing" means:

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

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

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

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

202 ~~[(36)]~~ (35) "Medical order" means a lawful order of a practitioner which may include a
203 prescription drug order.

204 ~~[(37)]~~ (36) "Medication profile" or "profile" means a record system maintained as to
205 drugs or devices prescribed for a pharmacy patient to enable a pharmacist or pharmacy intern to
206 analyze the profile to provide pharmaceutical care.

207 ~~[(38)]~~ (37) "Misbranded drug or device" means a drug or device considered
208 misbranded under 21 U.S.C.S. Sec. 352 (2003).

209 ~~[(39)]~~ (38) (a) "Nonprescription drug" means a drug which:

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

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

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

213 [~~(40)~~] (39) "Nonresident pharmacy" means a pharmacy located outside of Utah that
214 sells to a person in Utah.

215 [~~(41)~~] (40) "Nuclear pharmacy" means a pharmacy providing radio-pharmaceutical
216 service.

217 [~~(42)~~] (41) "Out-of-state mail service pharmacy" means a pharmaceutical facility
218 located outside the state that is licensed and in good standing in another state, that:

219 (a) ships, mails, or delivers by any lawful means a dispensed legend drug to a patient in
220 this state pursuant to a lawfully issued prescription;

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

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

226 [~~(43)~~] (42) "Patient counseling" means the written and oral communication by the
227 pharmacist or pharmacy intern of information, to the patient or caregiver, in order to ensure
228 proper use of drugs, devices, and dietary supplements.

229 [~~(44)~~] (43) "Pharmaceutical administration facility" means a facility, agency, or
230 institution in which:

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

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

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

239 [~~(45)~~] (44) (a) "Pharmaceutical care" means carrying out the following in collaboration
240 with a prescribing practitioner, and in accordance with division rule:

241 (i) designing, implementing, and monitoring a therapeutic drug plan intended to
242 achieve favorable outcomes related to a specific patient for the purpose of curing or preventing

243 the patient's disease;

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

245 (iii) arresting or slowing a disease process.

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

248 [~~(46)~~] (45) "Pharmaceutical facility" means a business engaged in the dispensing,
249 delivering, distributing, manufacturing, or wholesaling of prescription drugs or devices within
250 or into this state.

251 [~~(47)~~] (46) (a) "Pharmaceutical wholesaler or distributor" means a pharmaceutical
252 facility engaged in the business of wholesale vending or selling of [~~any~~] a prescription drug or
253 device to other than [~~the~~] a consumer or user of the prescription drug or device [~~,-which~~] that
254 the pharmaceutical facility has not produced, manufactured, compounded, or dispensed.

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

257 (i) intracompany sales;

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

262 (A) hospitals [~~or other health care facilities that are under common ownership or~~
263 ~~control of the management and operation of the facilities];~~

264 (B) pharmacies;

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

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

267 (iii) the sale, purchase, or trade of a prescription drug or device, or an offer to sell,
268 purchase, or trade a prescription drug or device, for emergency medical reasons, [~~or to supply~~
269 ~~another~~] including supplying another pharmaceutical facility [~~to alleviate a temporary shortage;~~
270 ~~or~~] with a limited quantity of a drug, if:

271 (A) the facility is unable to obtain the drug through a normal distribution channel ~~§→~~ [~~or~~
272 ~~other source~~] ~~←§~~ in sufficient time to eliminate the risk of harm to a patient that would result from a
273 delay in obtaining the drug; and

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

276 (iv) the distribution of a prescription drug or device as a sample by representatives of a
277 manufacturer[-]; and

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

279 (A) the dosage units distributed during a calendar year do not exceed five percent of
280 the sum of the dosage units distributed by the facility during the calendar year and the dosage
281 units dispensed by the facility during the calendar year; and

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

283 [~~(48)~~] (47) "Pharmacist" means an individual licensed by this state to engage in the
284 practice of pharmacy.

285 [~~(49)~~] (48) "Pharmacist-in-charge" means a pharmacist currently licensed in good
286 standing who accepts responsibility for the operation of a pharmacy in conformance with all
287 laws and rules pertinent to the practice of pharmacy and the distribution of drugs, and who is
288 personally in full and actual charge of the pharmacy and all personnel.

289 [~~(50)~~] (49) "Pharmacist preceptor" means a licensed pharmacist in good standing with
290 one or more years of licensed experience. The preceptor serves as a teacher, example of
291 professional conduct, and supervisor of interns in the professional practice of pharmacy.

292 [~~(51)~~] (50) "Pharmacy" means any place where:

293 (a) drugs are dispensed;

294 (b) pharmaceutical care is provided;

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

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

297 [~~(52)~~] (51) "Pharmacy benefits manager or coordinator" means a person or entity that
298 provides pharmacy benefit management services as defined in Section 49-20-502 on behalf of a
299 self-insured employer, insurance company, health maintenance organization, or other plan
300 sponsor, as defined by rule.

301 [~~(53)~~] (52) "Pharmacy intern" means an individual licensed by this state to engage in
302 practice as a pharmacy intern.

303 [~~(54)~~] (53) "Pharmacy technician training program" means an approved technician
304 training program providing education for pharmacy technicians.

305 ~~[(55)]~~ (54) (a) "Practice as a licensed pharmacy technician" means engaging in practice
306 as a pharmacy technician under the general supervision of a licensed pharmacist and in
307 accordance with a scope of practice defined by division rule made in collaboration with the
308 board.

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

310 (i) performing a drug utilization review, prescription drug order clarification from a
311 prescriber, final review of the prescription ~~[and prescribed drug prepared for dispensing]~~,
312 dispensing of the drug, or counseling a patient with respect to a prescription drug;

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

315 ~~[(ii)]~~ (iii) counseling regarding nonprescription drugs and dietary supplements unless
316 delegated by the supervising pharmacist; or

317 ~~[(iii)]~~ (iv) receiving new prescription drug orders when communicating telephonically
318 or electronically unless the original information is recorded so the pharmacist may review the
319 prescription drug order as transmitted.

320 ~~[(56)]~~ (55) "Practice of pharmacy" includes the following:

321 (a) providing pharmaceutical care;

322 (b) collaborative pharmacy practice in accordance with a collaborative pharmacy
323 practice agreement;

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

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

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

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

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

334 (d) participating in drug utilization review;

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

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

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

340 (h) providing drug product equivalents;

341 (i) supervising pharmacist's supportive personnel, pharmacy interns, and pharmacy
342 technicians;

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

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

345 (l) telepharmacy; and

346 (m) formulary management intervention.

347 [~~57~~] (56) "Practice of telepharmacy" means the practice of pharmacy through the use
348 of telecommunications and information technologies.

349 [~~58~~] (57) "Practice of telepharmacy across state lines" means the practice of
350 pharmacy through the use of telecommunications and information technologies that occurs
351 when the patient is physically located within one jurisdiction and the pharmacist is located in
352 another jurisdiction.

353 [~~59~~] (58) "Practitioner" means an individual currently licensed, registered, or
354 otherwise authorized by the appropriate jurisdiction to prescribe and administer drugs in the
355 course of professional practice.

356 [~~60~~] (59) "Prescribe" means to issue a prescription:

357 (a) orally or in writing; or

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

360 [~~61~~] (60) "Prescription" means an order issued:

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

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

365 [~~62~~] (61) "Prescription device" means an instrument, apparatus, implement, machine,
366 contrivance, implant, in vitro reagent, or other similar or related article, and any component

367 part or accessory, which is required under federal or state law to be prescribed by a practitioner
368 and dispensed by or through a person or entity licensed under this chapter or exempt from
369 licensure under this chapter.

370 ~~[(63)]~~ (62) "Prescription drug" means a drug that is required by federal or state law or
371 rule to be dispensed only by prescription or is restricted to administration only by practitioners.

372 ~~[(64)]~~ (63) "Retail pharmacy" means a pharmaceutical facility dispensing prescription
373 drugs and devices to the general public.

374 ~~[(65)]~~ (64) "Self-audit" means an internal evaluation of a pharmacy to determine
375 compliance with this chapter.

376 ~~[(66)]~~ (65) "Supervising pharmacist" means a pharmacist who is overseeing the
377 operation of the pharmacy during a given day or shift.

378 ~~[(67)]~~ (66) "Supportive personnel" means unlicensed individuals who:

379 (a) may assist a pharmacist, pharmacist preceptor, pharmacy intern, or licensed
380 pharmacy technician in nonjudgmental duties not included in the definition of the practice of
381 pharmacy, practice of a pharmacy intern, or practice of a licensed pharmacy technician, and as
382 those duties may be further defined by division rule adopted in collaboration with the board;
383 and

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

386 ~~[(68)]~~ (67) "Unlawful conduct" is as defined in Sections 58-1-501 and 58-17b-501.

387 ~~[(69)]~~ (68) "Unprofessional conduct" is as defined in Sections 58-1-501 and
388 58-17b-502 and may be further defined by rule.

389 ~~[(70)]~~ (69) "Veterinary pharmaceutical facility" means a pharmaceutical facility that
390 dispenses drugs intended for use by animals or for sale to veterinarians for the administration
391 for animals.

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

393 **58-17b-304. Qualifications for licensure of pharmacy intern.**

394 An applicant for licensure as a pharmacy intern shall:

395 (1) submit an application in a form prescribed by the division;

396 (2) pay a fee determined by the department under Section 63J-1-504;

397 (3) produce satisfactory evidence of good moral character as it relates to the applicant's

398 ability to practice pharmacy;

399 (4) complete a criminal background check and be free from criminal convictions as
400 described in Section 58-1-501;

401 (5) have no physical or mental condition of a nature which prevents the applicant from
402 engaging in the practice of pharmacy with reasonable skill, competency, and safety to the
403 public;

404 (6) meet the preliminary educational qualifications required by division rule made in
405 collaboration with the board; and

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

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

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

412 ~~[(c)]~~ (b) have graduated from a foreign pharmacy school and received certification of
413 equivalency from a credentialing agency approved by division rule made in collaboration with
414 the board.

415 Section 3. Section **58-17b-305** is amended to read:

416 **58-17b-305. Qualifications for licensure of pharmacy technician.**

417 (1) An applicant for licensure as a pharmacy technician shall:

418 (a) submit an application in a form prescribed by the division;

419 (b) pay a fee determined by the department under Section 63J-1-504;

420 (c) produce satisfactory evidence of good moral character as it relates to the applicant's
421 ability to practice pharmacy;

422 (d) complete a criminal background check and be free from criminal convictions as
423 described in Section 58-1-501;

424 (e) have no physical or mental condition of a nature which prevents the applicant from
425 engaging in practice as a pharmacy technician with reasonable skill, competency, and safety to
426 the public;

427 (f) have completed a ~~[board approved]~~ program and curriculum of education and
428 training, meeting standards established by division rule made in collaboration with the board;

429 and

430 (g) successfully complete the examinations requirement within the time periods
431 established by division rule made in collaboration with the board.

432 (2) A pharmacist whose license has been denied, revoked, suspended, or restricted for
433 disciplinary purposes is not eligible to be a licensed pharmacy technician while on probation
434 with the division.

435 Section 4. Section **58-17b-608.1** is enacted to read:

436 **58-17b-608.1. Refills of legend drug prescriptions.**

437 If a prescription for a legend drug includes authorization for one or more refills, a
438 pharmacist or pharmacy intern may dispense one or more of the refills at the time the drug is
439 dispensed, if:

440 (1) the drug is not a controlled substance;

441 (2) the prescription does not include "Dispense quantity written," or some other
442 notation having similar meaning;

443 (3) the total dosage units dispensed, including the units for both the prescription and
444 any refills, do not exceed a 100-day supply; and

445 (4) in the professional judgment of the pharmacist or pharmacy intern the refill, or
446 refills, should be dispensed at the time the prescription is dispensed.

447 Section 5. Section **58-17b-612** is amended to read:

448 **58-17b-612. Supervision -- Pharmacist-in-charge.**

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

453 (b) Notwithstanding Subsection [~~58-17b-102(66)~~] 58-17b-102(65), a supervising
454 pharmacist does not have to be in the pharmacy or care facility but shall be available via a
455 telepharmacy system for immediate contact with the supervised pharmacy technician or
456 pharmacy intern if:

457 (i) the pharmacy is located in:

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

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

460 (ii) the supervising pharmacist described in Subsection (1)(a) is not available; and
461 (iii) the telepharmacy system maintains records and files quarterly reports as required
462 by division rule to assure that patient safety is not compromised.

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

467 Section 6. Section **58-17b-622** is amended to read:

468 **58-17b-622. Pharmacy benefit management services -- Auditing of pharmacy**
469 **records -- Appeals.**

470 (1) For purposes of this section:

471 (a) "Audit" means a review of the records of a pharmacy by or on behalf of an entity
472 that finances or reimburses the cost of health care services or pharmaceutical products.

473 (b) "Entity" includes:

474 (i) a pharmacy benefits manager or coordinator;

475 (ii) a health benefit plan;

476 (iii) a third party administrator as defined in Section 31A-1-301;

477 (iv) a state agency; or

478 (v) a company, group, or agent that represents, or is engaged by, one of the entities
479 described in Subsections (1)(b)(i) through (iv).

480 (c) "Fraud" means an intentional act of deception, misrepresentation, or concealment in
481 order to gain something of value.

482 (d) "Health benefit plan" means:

483 (i) a health benefit plan as defined in Section 31A-1-301; or

484 (ii) a health, dental, medical, Medicare supplement, or conversion program offered
485 under Title 49, Chapter 20, Public Employees' Benefit and Insurance Program Act.

486 (2) (a) Except as provided in Subsection (2)(b), this section applies to:

487 (i) a contract for the audit of a pharmacy entered into, amended, or renewed on or after
488 July 1, 2012; and

489 (ii) an entity that conducts an audit of the pharmacy records of a pharmacy licensed
490 under this chapter.

- 491 (b) This section does not apply to an audit of pharmacy records:
492 (i) for a federally funded prescription drug program, including:
493 (A) the state Medicaid program;
494 (B) the Medicare Part D program;
495 (C) a Department of Defense prescription drug program;
496 (D) a Veteran's Affairs prescription drug program; or
497 (ii) when fraud or other intentional and willful misrepresentation is alleged and the
498 pharmacy audit entity has evidence that the pharmacy's actions reasonably indicate fraud or
499 intentional and willful misrepresentation.
- 500 (3) (a) An audit that involves clinical or professional judgment shall be conducted by
501 or in consultation with a licensed pharmacist who is employed by or working with the auditing
502 entity.
- 503 (b) If an audit is conducted on site at a pharmacy, the entity conducting the audit:
504 (i) shall give the pharmacy 10 days advanced written notice of:
505 (A) the audit; and
506 (B) the range of prescription numbers or a date range included in the audit; and
507 (ii) may not audit a pharmacy during the first five business days of the month, unless
508 the pharmacy agrees to the timing of the audit.
- 509 (c) An entity may not audit claims:
510 (i) submitted more than 18 months prior to the audit, unless:
511 (A) required by federal law; or
512 (B) the originating prescription is dated in the preceding six months; or
513 (ii) that exceed 200 selected prescription claims.
- 514 (4) (a) An entity may not:
515 (i) include dispensing fees in the calculations of overpayments unless the prescription
516 is considered a misfill;
517 (ii) recoup funds for prescription clerical or recordkeeping errors, including
518 typographical errors, scrivener's errors, and computer errors on a required document or record
519 unless the audit entity is alleging fraud or other intentional or willful misrepresentation and the
520 audit entity has evidence that the pharmacy's actions reasonably indicate fraud or intentional
521 and willful misrepresentation; [or]

522 (iii) recoup funds for refills dispensed in accordance with Section 58-17b-608.1 ~~§~~→ **[at the**
523 **time a prescription is dispensed;] , unless the health benefit plan does not cover the prescription**
523a **drug dispensed by the pharmacy;** ←~~§~~ **or**

524 [(iii)] (iv) collect any funds, charge-backs, or penalties until the audit and all appeals
525 are final, unless the audit entity is alleging fraud or other intentional or willful
526 misrepresentation and the audit entity has evidence that the pharmacy's actions reasonably
527 indicate fraud or intentional and willful misrepresentation.

528 (b) Auditors shall only have access to previous audit reports on a particular pharmacy
529 if the previous audit was conducted by the same entity except as required for compliance with
530 state or federal law.

531 (5) A pharmacy subject to an audit may use the following records to validate a claim
532 for a prescription, refill, or change in a prescription:

533 (a) electronic or physical copies of records of a health care facility, or a health care
534 provider with prescribing authority; and

535 (b) any prescription that complies with state law.

536 (6) (a) An entity that audits a pharmacy shall provide the pharmacy with a preliminary
537 audit report, delivered to the pharmacy or its corporate office of record within 60 days after
538 completion of the audit.

539 (b) A pharmacy has 30 days following receipt of the preliminary audit report to
540 respond to questions, provide additional documentation, and comment on and clarify findings
541 of the audit. Receipt of the report shall be based on the postmark date or the date of a
542 computer transmission if transferred electronically.

543 (7) If an audit results in the dispute or denial of a claim, the entity conducting the audit
544 shall allow the pharmacy to resubmit a claim using any commercially reasonable method,
545 including fax, mail, or electronic claims submission provided that the period of time when a
546 claim may be resubmitted has not expired under the rules of the plan sponsor.

547 (8) (a) Within 120 days after the completion of the appeals process under Subsection
548 (9), a final audit report shall be delivered to the pharmacy or its corporate office of record.

549 (b) The final audit report shall include a disclosure of any money recovered by the
550 entity that conducted the audit.

551 (9) An entity that audits a pharmacy shall establish a written appeals process for
552 appealing a preliminary audit report and a final audit report, and shall provide the pharmacy

553 with notice of the written appeals process. If the pharmacy benefit manager's contract or
554 provider manual contains the information required by this Subsection (9), the requirement for
555 notice is met.