

- 30 ▶ sets forth that a prescriber can prohibit the substitution of a biological product with
- 31 an interchangeable biosimilar product orally or in writing;
- 32 ▶ establishes requirements for the substitution of a biological product with an
- 33 interchangeable biosimilar product relating to:
- 34 • labeling;
- 35 • patient notification; and
- 36 • record keeping; and
- 37 ▶ makes technical changes.

38 **Money Appropriated in this Bill:**

39 None

40 **Other Special Clauses:**

41 None

42 **Utah Code Sections Affected:**

43 AMENDS:

44 **58-17b-102**, as last amended by Laws of Utah 2012, Chapters 265 and 320

45 **58-17b-605**, as last amended by Laws of Utah 2008, Chapter 205

46 **63I-2-258**, as last amended by Laws of Utah 2012, Chapters 88 and 369

47 ENACTS:

48 **58-17b-605.5**, Utah Code Annotated 1953



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

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

52 **58-17b-102. Definitions.**

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

54 (1) "Administering" means:

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

56 inhalation, ingestion, or by any other means, to the body of a human patient or research subject

57 by another person; or

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

62 (2) "Adulterated drug or device" means a drug or device considered adulterated under
63 21 U.S.C.S. Sec. 351 (2003).

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

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

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

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

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

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

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

86 approved by the division as the parent pharmacy.

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

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

94 (11) "Class B pharmacy":

95 (a) means a pharmacy located in Utah:

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

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

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

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

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

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

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

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

111 (16) "Collaborative pharmacy practice" means a practice of pharmacy whereby one or
112 more pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or
113 more practitioners under protocol whereby the pharmacist may perform certain pharmaceutical

114 care functions authorized by the practitioner or practitioners under certain specified conditions
115 or limitations.

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

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

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

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

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

128 (b) "Compounding" does not include:

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

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

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

136 (19) "Confidential information" has the same meaning as "protected health
137 information" under the Standards for Privacy of Individually Identifiable Health Information,
138 45 C.F.R. Parts 160 and 164.

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

140 (21) "Dietary supplement" has the same meaning as Public Law Title 103, Chapter
141 417, Sec. 3a(ff) which is incorporated by reference.

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

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

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

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

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

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

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

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

160 [~~(25) "Drug product equivalent" means a drug product that is designated as the~~
161 ~~therapeutic equivalent of another drug product in the Approved Drug Products with~~
162 ~~Therapeutic Equivalence Evaluations prepared by the Center for Drug Evaluation and Research~~
163 ~~of the Federal Food and Drug Administration.]~~

164 [(26)] (25) "Drug regimen review" includes the following activities:

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

166 (i) known allergies;

167 (ii) rational therapy-contraindications;

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

169 (iv) reasonable directions for use;

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

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

174 (i) drug-drug;

175 (ii) drug-food;

176 (iii) drug-disease; and

177 (iv) adverse drug reactions; and

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

180 [~~(27)~~] (26) "Drug sample" means a prescription drug packaged in small quantities
181 consistent with limited dosage therapy of the particular drug, which is marked "sample", is not
182 intended to be sold, and is intended to be provided to practitioners for the immediate needs of
183 patients for trial purposes or to provide the drug to the patient until a prescription can be filled
184 by the patient.

185 [~~(28)~~] (27) "Electronic signature" means a trusted, verifiable, and secure electronic
186 sound, symbol, or process attached to or logically associated with a record and executed or
187 adopted by a person with the intent to sign the record.

188 [~~(29)~~] (28) "Electronic transmission" means transmission of information in electronic
189 form or the transmission of the exact visual image of a document by way of electronic
190 equipment.

191 [~~(30)~~] (29) "Extern" means a college of pharmacy student enrolled in a college
192 coordinated practical experience program in a health care setting under the supervision of a
193 preceptor, as defined in this act, and approved by a college of pharmacy.

194 [~~(31)~~] (30) "Hospital pharmacy" means a pharmacy providing pharmaceutical care to
195 inpatients of a general acute hospital or specialty hospital licensed by the Department of Health
196 under Title 26, Chapter 21, Health Care Facility Licensing and Inspection Act.

197 [~~(32)~~] (31) "Legend drug" has the same meaning as prescription drug.

198 [~~(33)~~] (32) "Licensed pharmacy technician" means an individual licensed with the
199 division, that may, under the supervision of a pharmacist, perform the activities involved in the
200 technician practice of pharmacy.

201 [~~(34)~~] (33) "Manufacturer" means a person or business physically located in Utah
202 licensed to be engaged in the manufacturing of drugs or devices.

203 [~~(35)~~] (34) (a) "Manufacturing" means:

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

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

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

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

216 [~~(36)~~] (35) "Medical order" means a lawful order of a practitioner which may include a
217 prescription drug order.

218 [~~(37)~~] (36) "Medication profile" or "profile" means a record system maintained as to
219 drugs or devices prescribed for a pharmacy patient to enable a pharmacist or pharmacy intern to
220 analyze the profile to provide pharmaceutical care.

221 [~~(38)~~] (37) "Misbranded drug or device" means a drug or device considered
222 misbranded under 21 U.S.C.S. Sec. 352 (2003).

223 [~~(39)~~] (38) (a) "Nonprescription drug" means a drug which:

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

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

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

227 [~~(40)~~] (39) "Nonresident pharmacy" means a pharmacy located outside of Utah that
228 sells to a person in Utah.

229 [~~(41)~~] (40) "Nuclear pharmacy" means a pharmacy providing radio-pharmaceutical
230 service.

231 [~~(42)~~] (41) "Out-of-state mail service pharmacy" means a pharmaceutical facility
232 located outside the state that is licensed and in good standing in another state, that:

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

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

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

240 [~~(43)~~] (42) "Patient counseling" means the written and oral communication by the
241 pharmacist or pharmacy intern of information, to the patient or caregiver, in order to ensure
242 proper use of drugs, devices, and dietary supplements.

243 [~~(44)~~] (43) "Pharmaceutical administration facility" means a facility, agency, or
244 institution in which:

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

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

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

253 [~~(45)~~] (44) (a) "Pharmaceutical care" means carrying out the following in collaboration

254 with a prescribing practitioner, and in accordance with division rule:

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

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

259 (iii) arresting or slowing a disease process.

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

262 [~~(46)~~] (45) "Pharmaceutical facility" means a business engaged in the dispensing,
263 delivering, distributing, manufacturing, or wholesaling of prescription drugs or devices within
264 or into this state.

265 [~~(47)~~] (46) (a) "Pharmaceutical wholesaler or distributor" means a pharmaceutical
266 facility engaged in the business of wholesale vending or selling of any prescription drug or
267 device to other than the consumer or user of the prescription drug or device, which the
268 pharmaceutical facility has not produced, manufactured, compounded, or dispensed.

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

271 (i) intracompany sales;

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

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

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

280 [~~(48)~~] (47) "Pharmacist" means an individual licensed by this state to engage in the
281 practice of pharmacy.

282 [~~(49)~~] (48) "Pharmacist-in-charge" means a pharmacist currently licensed in good
283 standing who accepts responsibility for the operation of a pharmacy in conformance with all
284 laws and rules pertinent to the practice of pharmacy and the distribution of drugs, and who is
285 personally in full and actual charge of the pharmacy and all personnel.

286 [~~(50)~~] (49) "Pharmacist preceptor" means a licensed pharmacist in good standing with
287 one or more years of licensed experience. The preceptor serves as a teacher, example of
288 professional conduct, and supervisor of interns in the professional practice of pharmacy.

289 [~~(51)~~] (50) "Pharmacy" means any place where:

- 290 (a) drugs are dispensed;
- 291 (b) pharmaceutical care is provided;
- 292 (c) drugs are processed or handled for eventual use by a patient; or
- 293 (d) drugs are used for the purpose of analysis or research.

294 [~~(52)~~] (51) "Pharmacy benefits manager or coordinator" means a person or entity that
295 provides pharmacy benefit management services as defined in Section 49-20-502 on behalf of a
296 self-insured employer, insurance company, health maintenance organization, or other plan
297 sponsor, as defined by rule.

298 [~~(53)~~] (52) "Pharmacy intern" means an individual licensed by this state to engage in
299 practice as a pharmacy intern.

300 [~~(54)~~] (53) "Pharmacy technician training program" means an approved technician
301 training program providing education for pharmacy technicians.

302 [~~(55)~~] (54) (a) "Practice as a licensed pharmacy technician" means engaging in practice
303 as a pharmacy technician under the general supervision of a licensed pharmacist and in
304 accordance with a scope of practice defined by division rule made in collaboration with the
305 board.

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

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

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

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

315 [~~56~~] (55) "Practice of pharmacy" includes the following:

316 (a) providing pharmaceutical care;

317 (b) collaborative pharmacy practice in accordance with a collaborative pharmacy
318 practice agreement;

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

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

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

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

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

329 (d) participating in drug utilization review;

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

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

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

335 (h) providing drug product equivalents;

336 (i) supervising pharmacist's supportive personnel, pharmacy interns, and pharmacy
337 technicians;

- 338 (j) providing patient counseling, including adverse and therapeutic effects of drugs;
- 339 (k) providing emergency refills as defined by rule;
- 340 (l) telepharmacy; and
- 341 (m) formulary management intervention.

342 [~~(57)~~] (56) "Practice of telepharmacy" means the practice of pharmacy through the use
343 of telecommunications and information technologies.

344 [~~(58)~~] (57) "Practice of telepharmacy across state lines" means the practice of
345 pharmacy through the use of telecommunications and information technologies that occurs
346 when the patient is physically located within one jurisdiction and the pharmacist is located in
347 another jurisdiction.

348 [~~(59)~~] (58) "Practitioner" means an individual currently licensed, registered, or
349 otherwise authorized by the appropriate jurisdiction to prescribe and administer drugs in the
350 course of professional practice.

351 [~~(60)~~] (59) "Prescribe" means to issue a prescription:

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

355 [~~(61)~~] (60) "Prescription" means an order issued:

- 356 (a) by a licensed practitioner in the course of that practitioner's professional practice or
357 by collaborative pharmacy practice agreement; and
- 358 (b) for a controlled substance or other prescription drug or device for use by a patient
359 or an animal.

360 [~~(62)~~] (61) "Prescription device" means an instrument, apparatus, implement, machine,
361 contrivance, implant, in vitro reagent, or other similar or related article, and any component
362 part or accessory, which is required under federal or state law to be prescribed by a practitioner
363 and dispensed by or through a person or entity licensed under this chapter or exempt from
364 licensure under this chapter.

365 [~~(63)~~] (62) "Prescription drug" means a drug that is required by federal or state law or

366 rule to be dispensed only by prescription or is restricted to administration only by practitioners.

367 ~~[(64)]~~ (63) "Retail pharmacy" means a pharmaceutical facility dispensing prescription
368 drugs and devices to the general public.

369 ~~[(65)]~~ (64) "Self-audit" means an internal evaluation of a pharmacy to determine
370 compliance with this chapter.

371 ~~[(66)]~~ (65) "Supervising pharmacist" means a pharmacist who is overseeing the
372 operation of the pharmacy during a given day or shift.

373 ~~[(67)]~~ (66) "Supportive personnel" means unlicensed individuals who:

374 (a) may assist a pharmacist, pharmacist preceptor, pharmacy intern, or licensed
375 pharmacy technician in nonjudgmental duties not included in the definition of the practice of
376 pharmacy, practice of a pharmacy intern, or practice of a licensed pharmacy technician, and as
377 those duties may be further defined by division rule adopted in collaboration with the board;
378 and

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

381 ~~[(68)]~~ (67) "Unlawful conduct" is as defined in Sections 58-1-501 and 58-17b-501.

382 ~~[(69)]~~ (68) "Unprofessional conduct" is as defined in Sections 58-1-501 and
383 58-17b-502 and may be further defined by rule.

384 ~~[(70)]~~ (69) "Veterinary pharmaceutical facility" means a pharmaceutical facility that
385 dispenses drugs intended for use by animals or for sale to veterinarians for the administration
386 for animals.

387 Section 2. Section **58-17b-605** is amended to read:

388 **58-17b-605. Drug product equivalents.**

389 (1) For the purposes of this section:

390 (a) (i) "Drug" is as defined in Section 58-17b-102.

391 (ii) "Drug" does not mean a "biological product" as defined in Section 58-17b-605.5.

392 (b) "Drug product equivalent" means a drug product that is designated as the
393 therapeutic equivalent of another drug product in the Approved Drug Products with

394 Therapeutic Equivalence Evaluations prepared by the Center for Drug Evaluation and Research
395 of the United States Food and Drug Administration.

396 [~~(1)~~] (2) A pharmacist or pharmacy intern dispensing a prescription order for a specific
397 drug by brand or proprietary name may substitute a drug product equivalent~~[, as defined in~~
398 ~~Section 58-17b-102,]~~ for the prescribed drug only if:

399 (a) the purchaser specifically requests or consents to the substitution of a drug product
400 equivalent;

401 (b) the drug product equivalent is of the same generic type and is designated the
402 therapeutic equivalent in the approved drug products with therapeutic equivalence evaluations
403 prepared by the Center for Drug Evaluation and Research of the Federal Food and Drug
404 Administration;

405 (c) the drug product equivalent is permitted to move in interstate commerce;

406 (d) the pharmacist or pharmacy intern counsels the patient on the use and the expected
407 response to the prescribed drug, whether a substitute or not, and the substitution is not
408 otherwise prohibited by this chapter;

409 (e) the prescribing practitioner has not indicated that a drug product equivalent may not
410 be substituted for the drug, as provided in Subsection [~~(5)~~] (6); and

411 (f) the substitution is not otherwise prohibited by law.

412 [~~(2)~~] (3) (a) Each out-of-state mail service pharmacy dispensing a drug product
413 equivalent as a substitute for another drug into this state shall notify the patient of the
414 substitution either by telephone or in writing.

415 (b) Each out-of-state mail service pharmacy shall comply with the requirements of this
416 chapter with respect to a drug product equivalent substituted for another drug, including
417 labeling and record keeping.

418 [~~(3)~~] (4) Pharmacists or pharmacy interns may not substitute without the prescriber's
419 authorization on trade name drug product prescriptions unless the product is currently
420 categorized in the approved drug products with therapeutic equivalence evaluations prepared
421 by the Center for Drug Evaluation and Research of the Federal Food and Drug Administration

422 as a drug product considered to be therapeutically equivalent to another drug product.

423 ~~[(4)]~~ (5) A pharmacist or pharmacy intern who dispenses a prescription with a drug
424 product equivalent under this section assumes no greater liability than would be incurred had
425 the pharmacist or pharmacy intern dispensed the prescription with the drug product prescribed.

426 ~~[(5)]~~ (6) (a) If, in the opinion of the prescribing practitioner, it is in the best interest of
427 the patient that a drug product equivalent not be substituted for a prescribed drug, the
428 practitioner may indicate a prohibition on substitution either by writing "dispense as written" or
429 signing in the appropriate space where two lines have been preprinted on a prescription order
430 and captioned "dispense as written" or "substitution permitted".

431 (b) If the prescription is communicated orally by the prescribing practitioner to the
432 pharmacist or pharmacy intern, the practitioner shall indicate the prohibition on substitution
433 and that indication shall be noted in writing by the pharmacist or pharmacy intern with the
434 name of the practitioner and the words "orally by" and the initials of the pharmacist or
435 pharmacy intern written after it.

436 ~~[(6)]~~ (7) A pharmacist or pharmacy intern who substitutes a drug product equivalent
437 for a prescribed drug shall communicate the substitution to the purchaser. The drug product
438 equivalent container shall be labeled with the name of the drug dispensed, and the pharmacist,
439 pharmacy intern, or pharmacy technician shall indicate on the file copy of the prescription both
440 the name of the prescribed drug and the name of the drug product equivalent dispensed in its
441 place.

442 ~~[(7)]~~ (8) (a) For purposes of this Subsection ~~[(7)]~~ (8), "substitutes" means to substitute:

- 443 (i) a generic drug for another generic drug;
- 444 (ii) a generic drug for a nongeneric drug;
- 445 (iii) a nongeneric drug for another nongeneric drug; or
- 446 (iv) a nongeneric drug for a generic drug.

447 (b) A prescribing practitioner who makes a finding under Subsection ~~[(5)]~~ (6)(a) for a
448 patient with a seizure disorder shall indicate a prohibition on substitution of a drug product
449 equivalent in the manner provided in Subsection ~~[(5)]~~ (6)(a) or (b).

450 (c) Except as provided in Subsection [~~(7)~~] (8)(d), a pharmacist or pharmacy intern who
451 cannot dispense the prescribed drug as written, and who needs to substitute a drug product
452 equivalent for the drug prescribed to the patient to treat or prevent seizures shall notify the
453 prescribing practitioner prior to the substitution.

454 (d) Notification under Subsection [~~(7)~~] (8)(c) is not required if the drug product
455 equivalent is paid for in whole or in part by Medicaid.

456 [~~(8)~~] (9) Failure of a licensed medical practitioner to specify that no substitution is
457 authorized does not constitute evidence of negligence.

458 Section 3. Section **58-17b-605.5** is enacted to read:

459 **58-17b-605.5. Interchangeable biosimilar products.**

460 (1) For the purposes of this section:

461 (a) "biological product" is as defined in 21 U.S.C. Sec. 262;

462 (b) "biosimilar" is as defined in 21 U.S.C. Sec. 262; and

463 (c) "interchangeable" is as defined in 21 U.S.C. Sec. 262.

464 (2) A pharmacist or pharmacy intern dispensing a prescription order for a specific
465 biological product by brand or proprietary name may substitute a biosimilar product for the
466 prescribed biological product only if:

467 (a) the purchaser specifically requests or consents to the substitute of an
468 interchangeable biosimilar product;

469 (b) the biosimilar product has been determined by the United States Food and Drug
470 Administration to be interchangeable with the prescribed biological product;

471 (c) the interchangeable biosimilar product is permitted to move in interstate commerce;

472 (d) the pharmacist or pharmacy intern counsels the patient on the use and the expected
473 response to the prescribed biological product, whether a substitute or not, and the substitution
474 is not otherwise prohibited by this chapter;

475 (e) the prescribing practitioner has not prohibited the substitution of an interchangeable
476 biosimilar product for the prescribed biological product, as provided in Subsection (6); and

477 (f) the substitution is not otherwise prohibited by law.

478 (3) (a) Each out-of-state mail service pharmacy dispensing an interchangeable
479 biosimilar product as a substitute for another biological product into this state shall notify the
480 patient of the substitution either by telephone or in writing.

481 (b) Each out-of-state mail service pharmacy shall comply with the requirements of this
482 chapter with respect to an interchangeable biosimilar product substituted for another biological
483 product, including labeling and record keeping.

484 (4) Pharmacists or pharmacy interns may not substitute without the prescriber's
485 authorization biological product prescriptions unless the product has been determined by the
486 United States Food and Drug Administration to be interchangeable with the prescribed
487 biological product.

488 (5) A pharmacist or pharmacy intern who dispenses a prescription with an
489 interchangeable biosimilar product under this section assumes no greater liability than would
490 be incurred had the pharmacist or pharmacy intern dispensed the prescription with the
491 biological product prescribed.

492 (6) (a) If, in the opinion of the prescribing practitioner, it is in the best interest of the
493 patient that an interchangeable biosimilar product not be substituted for a prescribed biological
494 product, the practitioner may prohibit a substitution either by writing "dispense as written" or
495 by signing in the appropriate space where two lines have been preprinted on a prescription
496 order and captioned "dispense as written" or "substitution permitted."

497 (b) (i) If the prescription is communicated orally by the prescribing practitioner to the
498 pharmacist or pharmacy intern, the practitioner shall direct the prohibition or substitution.

499 (ii) The pharmacist or pharmacy intern shall make a written note of the practitioner's
500 direction by writing the name of the practitioner and the words "orally by" and the initials of
501 the pharmacist or pharmacy intern written after it.

502 (7) A pharmacist or pharmacy intern who substitutes an interchangeable biosimilar
503 product for a prescribed biological product shall communicate the substitution to the purchaser.
504 The interchangeable biosimilar product container shall be labeled with the name of the
505 interchangeable biosimilar product dispensed, and the pharmacist, pharmacy intern, or

506 pharmacy technician shall indicate on the file copy of the prescription both the name of the
507 prescribed biological product and the name of the interchangeable biosimilar product dispensed
508 in its place.

509 (8) (a) A pharmacist or pharmacy intern who substitutes an interchangeable biosimilar
510 product for a prescribed biological product shall:

511 (i) notify the prescriber in writing, by fax, telephone, or electronic transmission of the
512 substitution, as soon as practicable, but not later than three business days after dispensing the
513 interchangeable biosimilar product in place of the prescribed biological product; and

514 (ii) include the name and manufacturer of the interchangeable biosimilar product
515 substituted.

516 (b) This subsection is repealed on May 15, 2015.

517 Section 4. Section **63I-2-258** is amended to read:

518 **63I-2-258. Repeal dates -- Title 58.**

519 (1) Subsection 58-72-201(1)(b) is repealed July 1, 2014.

520 (2) Subsection 58-17b-605.5(8) is repealed on May 15, 2015.