

PHARMACY ACT AMENDMENTS

2013 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: J. Stuart Adams

House Sponsor: _____

LONG TITLE

General Description:

This bill amends the Pharmacy Practice Act to allow the substitution of interchangeable biosimilar products in the place of prescribed biological products.

Highlighted Provisions:

This bill:

- ▶ allows a pharmacist or pharmacy intern dispensing a prescription to substitute a biosimilar product in the place of a prescribed biological product if:
 - the United States Food and Drug Administration (FDA) has determined that the biosimilar product is interchangeable with the prescribed product;
 - the interchangeable biosimilar product is approved to move through interstate commerce;
 - the prescribing practitioner has not prohibited the substitution; and
 - the substitution is not prohibited by law;
- ▶ requires out-of-state mail pharmacies substituting interchangeable biosimilar products in the place of prescribed biological products to notify the patient and to keep records of the substitution;
- ▶ prohibits the substitution of a biosimilar product for the prescribed biological product without the prescriber's authorization unless the FDA has determined the biosimilar product to be interchangeable with the prescribed biological product;
- ▶ assigns no greater liability to a pharmacist or pharmacy intern who substitutes an



28 interchangeable biosimilar product in the place of a prescribed biological product than would
29 be incurred without the substitution;

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 ENACTS:

47 **58-17b-605.5**, Utah Code Annotated 1953



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

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

51 **58-17b-102. Definitions.**

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

53 (1) "Administering" means:

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

57 (b) the placement by a veterinarian with the owner or caretaker of an animal or group
58 of animals of a prescription drug for the purpose of injection, inhalation, ingestion, or any other

59 means directed to the body of the animal by the owner or caretaker in accordance with written
60 or verbal directions of the veterinarian.

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

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

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

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

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

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

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

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

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

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

93 (11) "Class B pharmacy":

94 (a) means a pharmacy located in Utah:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

127 (b) "Compounding" does not include:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

163 ~~[(26)]~~ (25) "Drug regimen review" includes the following activities:

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

165 (i) known allergies;

166 (ii) rational therapy-contraindications;

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

168 (iv) reasonable directions for use;

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

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

173 (i) drug-drug;

174 (ii) drug-food;

175 (iii) drug-disease; and

176 (iv) adverse drug reactions; and

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

179 ~~[(27)]~~ (26) "Drug sample" means a prescription drug packaged in small quantities
180 consistent with limited dosage therapy of the particular drug, which is marked "sample", is not
181 intended to be sold, and is intended to be provided to practitioners for the immediate needs of
182 patients for trial purposes or to provide the drug to the patient until a prescription can be filled

183 by the patient.

184 ~~[(28)]~~ (27) "Electronic signature" means a trusted, verifiable, and secure electronic
185 sound, symbol, or process attached to or logically associated with a record and executed or
186 adopted by a person with the intent to sign the record.

187 ~~[(29)]~~ (28) "Electronic transmission" means transmission of information in electronic
188 form or the transmission of the exact visual image of a document by way of electronic
189 equipment.

190 ~~[(30)]~~ (29) "Extern" means a college of pharmacy student enrolled in a college
191 coordinated practical experience program in a health care setting under the supervision of a
192 preceptor, as defined in this act, and approved by a college of pharmacy.

193 ~~[(31)]~~ (30) "Hospital pharmacy" means a pharmacy providing pharmaceutical care to
194 inpatients of a general acute hospital or specialty hospital licensed by the Department of Health
195 under Title 26, Chapter 21, Health Care Facility Licensing and Inspection Act.

196 ~~[(32)]~~ (31) "Legend drug" has the same meaning as prescription drug.

197 ~~[(33)]~~ (32) "Licensed pharmacy technician" means an individual licensed with the
198 division, that may, under the supervision of a pharmacist, perform the activities involved in the
199 technician practice of pharmacy.

200 ~~[(34)]~~ (33) "Manufacturer" means a person or business physically located in Utah
201 licensed to be engaged in the manufacturing of drugs or devices.

202 ~~[(35)]~~ (34) (a) "Manufacturing" means:

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

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

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

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

214 analysis.

215 ~~[(36)]~~ (35) "Medical order" means a lawful order of a practitioner which may include a
216 prescription drug order.

217 ~~[(37)]~~ (36) "Medication profile" or "profile" means a record system maintained as to
218 drugs or devices prescribed for a pharmacy patient to enable a pharmacist or pharmacy intern to
219 analyze the profile to provide pharmaceutical care.

220 ~~[(38)]~~ (37) "Misbranded drug or device" means a drug or device considered
221 misbranded under 21 U.S.C.S. Sec. 352 (2003).

222 ~~[(39)]~~ (38) (a) "Nonprescription drug" means a drug which:

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

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

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

226 ~~[(40)]~~ (39) "Nonresident pharmacy" means a pharmacy located outside of Utah that
227 sells to a person in Utah.

228 ~~[(41)]~~ (40) "Nuclear pharmacy" means a pharmacy providing radio-pharmaceutical
229 service.

230 ~~[(42)]~~ (41) "Out-of-state mail service pharmacy" means a pharmaceutical facility
231 located outside the state that is licensed and in good standing in another state, that:

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

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

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

239 ~~[(43)]~~ (42) "Patient counseling" means the written and oral communication by the
240 pharmacist or pharmacy intern of information, to the patient or caregiver, in order to ensure
241 proper use of drugs, devices, and dietary supplements.

242 ~~[(44)]~~ (43) "Pharmaceutical administration facility" means a facility, agency, or
243 institution in which:

244 (a) prescription drugs or devices are held, stored, or are otherwise under the control of

245 the facility or agency for administration to patients of that facility or agency;

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

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

252 [~~45~~] (44) (a) "Pharmaceutical care" means carrying out the following in collaboration
253 with a prescribing practitioner, and in accordance with division rule:

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

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

258 (iii) arresting or slowing a disease process.

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

261 [~~46~~] (45) "Pharmaceutical facility" means a business engaged in the dispensing,
262 delivering, distributing, manufacturing, or wholesaling of prescription drugs or devices within
263 or into this state.

264 [~~47~~] (46) (a) "Pharmaceutical wholesaler or distributor" means a pharmaceutical
265 facility engaged in the business of wholesale vending or selling of any prescription drug or
266 device to other than the consumer or user of the prescription drug or device, which the
267 pharmaceutical facility has not produced, manufactured, compounded, or dispensed.

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

270 (i) intracompany sales;

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

274 (iii) the sale, purchase, or trade of a prescription drug or device, or offer to sell,
275 purchase, or trade a prescription drug or device for emergency medical reasons, or to supply

276 another pharmaceutical facility to alleviate a temporary shortage; or

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

279 [~~(48)~~] (47) "Pharmacist" means an individual licensed by this state to engage in the
280 practice of pharmacy.

281 [~~(49)~~] (48) "Pharmacist-in-charge" means a pharmacist currently licensed in good
282 standing who accepts responsibility for the operation of a pharmacy in conformance with all
283 laws and rules pertinent to the practice of pharmacy and the distribution of drugs, and who is
284 personally in full and actual charge of the pharmacy and all personnel.

285 [~~(50)~~] (49) "Pharmacist preceptor" means a licensed pharmacist in good standing with
286 one or more years of licensed experience. The preceptor serves as a teacher, example of
287 professional conduct, and supervisor of interns in the professional practice of pharmacy.

288 [~~(51)~~] (50) "Pharmacy" means any place where:

289 (a) drugs are dispensed;

290 (b) pharmaceutical care is provided;

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

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

293 [~~(52)~~] (51) "Pharmacy benefits manager or coordinator" means a person or entity that
294 provides pharmacy benefit management services as defined in Section 49-20-502 on behalf of a
295 self-insured employer, insurance company, health maintenance organization, or other plan
296 sponsor, as defined by rule.

297 [~~(53)~~] (52) "Pharmacy intern" means an individual licensed by this state to engage in
298 practice as a pharmacy intern.

299 [~~(54)~~] (53) "Pharmacy technician training program" means an approved technician
300 training program providing education for pharmacy technicians.

301 [~~(55)~~] (54) (a) "Practice as a licensed pharmacy technician" means engaging in practice
302 as a pharmacy technician under the general supervision of a licensed pharmacist and in
303 accordance with a scope of practice defined by division rule made in collaboration with the
304 board.

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

306 (i) performing a drug utilization review, prescription drug order clarification from a

307 prescriber, final review of the prescription and prescribed drug prepared for dispensing,
308 dispensing of the drug, or counseling a patient with respect to a prescription drug;

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

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

314 [~~56~~] 55 "Practice of pharmacy" includes the following:

315 (a) providing pharmaceutical care;

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

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

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

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

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

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

328 (d) participating in drug utilization review;

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

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

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

334 (h) providing drug product equivalents;

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

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

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

339 (l) telepharmacy; and

340 (m) formulary management intervention.

341 [~~(57)~~] (56) "Practice of telepharmacy" means the practice of pharmacy through the use
342 of telecommunications and information technologies.

343 [~~(58)~~] (57) "Practice of telepharmacy across state lines" means the practice of
344 pharmacy through the use of telecommunications and information technologies that occurs
345 when the patient is physically located within one jurisdiction and the pharmacist is located in
346 another jurisdiction.

347 [~~(59)~~] (58) "Practitioner" means an individual currently licensed, registered, or
348 otherwise authorized by the appropriate jurisdiction to prescribe and administer drugs in the
349 course of professional practice.

350 [~~(60)~~] (59) "Prescribe" means to issue a prescription:

351 (a) orally or in writing; or

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

354 [~~(61)~~] (60) "Prescription" means an order issued:

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

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

359 [~~(62)~~] (61) "Prescription device" means an instrument, apparatus, implement, machine,
360 contrivance, implant, in vitro reagent, or other similar or related article, and any component
361 part or accessory, which is required under federal or state law to be prescribed by a practitioner
362 and dispensed by or through a person or entity licensed under this chapter or exempt from
363 licensure under this chapter.

364 [~~(63)~~] (62) "Prescription drug" means a drug that is required by federal or state law or
365 rule to be dispensed only by prescription or is restricted to administration only by practitioners.

366 [~~(64)~~] (63) "Retail pharmacy" means a pharmaceutical facility dispensing prescription
367 drugs and devices to the general public.

368 [~~(65)~~] (64) "Self-audit" means an internal evaluation of a pharmacy to determine

369 compliance with this chapter.

370 [(66)] (65) "Supervising pharmacist" means a pharmacist who is overseeing the
371 operation of the pharmacy during a given day or shift.

372 [(67)] (66) "Supportive personnel" means unlicensed individuals who:

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

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

380 [(68)] (67) "Unlawful conduct" is as defined in Sections 58-1-501 and 58-17b-501.

381 [(69)] (68) "Unprofessional conduct" is as defined in Sections 58-1-501 and
382 58-17b-502 and may be further defined by rule.

383 [(70)] (69) "Veterinary pharmaceutical facility" means a pharmaceutical facility that
384 dispenses drugs intended for use by animals or for sale to veterinarians for the administration
385 for animals.

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

387 **58-17b-605. Drug product equivalents.**

388 (1) For the purposes of this section:

389 (a) (i) "Drug" is as defined in Section 58-17b-102; and

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

391 (b) "Drug product equivalent" means a drug product that is designated as the

392 therapeutic equivalent of another drug product in the Approved Drug Products with

393 Therapeutic Equivalence Evaluations prepared by the Center for Drug Evaluation and Research

394 of the United States Food and Drug Administration.

395 [(1)] (2) A pharmacist or pharmacy intern dispensing a prescription order for a specific
396 drug by brand or proprietary name may substitute a drug product equivalent[~~as defined in~~
397 ~~Section 58-17b-102;~~] for the prescribed drug only if:

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

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

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

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

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

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

411 [~~(2)~~] (3) (a) Each out-of-state mail service pharmacy dispensing a drug product
412 equivalent as a substitute for another drug into this state shall notify the patient of the
413 substitution either by telephone or in writing.

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

417 [~~(3)~~] (4) Pharmacists or pharmacy interns may not substitute without the prescriber's
418 authorization on trade name drug product prescriptions unless the product is currently
419 categorized in the approved drug products with therapeutic equivalence evaluations prepared
420 by the Center for Drug Evaluation and Research of the Federal Food and Drug Administration
421 as a drug product considered to be therapeutically equivalent to another drug product.

422 [~~(4)~~] (5) A pharmacist or pharmacy intern who dispenses a prescription with a drug
423 product equivalent under this section assumes no greater liability than would be incurred had
424 the pharmacist or pharmacy intern dispensed the prescription with the drug product prescribed.

425 [~~(5)~~] (6) (a) If, in the opinion of the prescribing practitioner, it is in the best interest of
426 the patient that a drug product equivalent not be substituted for a prescribed drug, the
427 practitioner may indicate a prohibition on substitution either by writing "dispense as written" or
428 signing in the appropriate space where two lines have been preprinted on a prescription order
429 and captioned "dispense as written" or "substitution permitted".

430 (b) If the prescription is communicated orally by the prescribing practitioner to the

431 pharmacist or pharmacy intern, the practitioner shall indicate the prohibition on substitution
432 and that indication shall be noted in writing by the pharmacist or pharmacy intern with the
433 name of the practitioner and the words "orally by" and the initials of the pharmacist or
434 pharmacy intern written after it.

435 ~~[(6)]~~ (7) A pharmacist or pharmacy intern who substitutes a drug product equivalent
436 for a prescribed drug shall communicate the substitution to the purchaser. The drug product
437 equivalent container shall be labeled with the name of the drug dispensed, and the pharmacist,
438 pharmacy intern, or pharmacy technician shall indicate on the file copy of the prescription both
439 the name of the prescribed drug and the name of the drug product equivalent dispensed in its
440 place.

441 ~~[(7)]~~ (8) (a) For purposes of this Subsection ~~[(7)]~~ (8), "substitutes" means to substitute:

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

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

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

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

455 ~~[(8)]~~ (9) Failure of a licensed medical practitioner to specify that no substitution is
456 authorized does not constitute evidence of negligence.

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

458 **58-17b-605.5. Interchangeable biosimilar products.**

459 (1) For the purposes of this section:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

491 (6) (a) If, in the opinion of the prescribing practitioner, it is in the best interest of the
492 patient that an interchangeable biosimilar product not be substituted for a prescribed biological

493 product, the practitioner may prohibit a substitution either by writing "dispense as written" or
 494 by signing in the appropriate space where two lines have been preprinted on a prescription
 495 order and captioned "dispense as written" or "substitution permitted."

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

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

501 (7) A pharmacist or pharmacy intern who substitutes an interchangeable biosimilar
 502 product for a prescribed biological product shall ~~§~~→ **communicate the substitution to the**
 502a **purchaser. The interchangeable biosimilar product container shall be labeled with the name of**
 502b **the interchangeable biosimilar product dispensed, and the pharmacist, pharmacy intern, or**
 502c **pharmacy technician shall indicate on the file copy of the prescription both the name of the**
 502d **prescribed biological product and the name of the interchangeable biosimilar product**
 502e **dispensed in its place. [:**

503 —— ~~(a) communicate the substitution to the purchaser;~~

504 —— ~~(b) ensure that the interchangeable product container is labeled with the name and the~~
 505 ~~manufacturer of the interchangeable biosimilar product dispensed; and~~

506 —— ~~(c) indicate on the file copy of the prescription:~~

507 —— ~~(i) the name and the manufacturer of the prescribed biological product; and~~

508 —— ~~(ii) the name and the manufacturer of the interchangeable biosimilar product dispensed~~
 509 ~~in place of the prescribed biological product.] ←§~~

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

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

515 (b) include the name and manufacturer of the interchangeable biosimilar product
 516 substituted.

517 ~~§~~→ ~~(9) The pharmacist or pharmacy intern shall:~~

518 —— ~~(a) retain a written record of the substitution for at least five years; and~~

519 —— ~~(b) include the name and manufacturer of the interchangeable product substituted.~~

520 —— ~~(10)~~ (9) ←§ A licensed medical practitioner who fails to specify that no substitution is
 521 authorized does not constitute evidence of negligence.

Legislative Review Note
as of 2-14-13 1:42 PM

Office of Legislative Research and General Counsel