

1 **PHARMACY PRACTICE ACT AMENDMENTS**

2 2020 GENERAL SESSION

3 STATE OF UTAH

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

5 House Sponsor: Suzanne Harrison

7 **LONG TITLE**

8 **General Description:**

9 This bill amends provisions relating to the practice of pharmacy.

10 **Highlighted Provisions:**

11 This bill:

- 12 ▶ amends definitions;
- 13 ▶ authorizes the dispensing of epinephrine auto-injectors and stock albuterol under
14 certain circumstances;
- 15 ▶ amends provisions related to out-of-state mail service pharmacies;
- 16 ▶ amends provisions related to a prescription drug or device that is not readily
17 available in all pharmacies;
- 18 ▶ authorizes the dispensing of a quantity or dosage form different from a prescription
19 in certain instances;
- 20 ▶ amends provisions related to the dispensing of a substitute for albuterol;
- 21 ▶ amends provisions relating to emergency refills;
- 22 ▶ authorizes the dispensing of certain prescription medical devices under certain
23 circumstances;
- 24 ▶ authorizes certain physicians to issue a standing prescription drug order for an
25 epinephrine auto-injector or stock albuterol in accordance with a protocol that meets
26 certain requirements;
- 27 ▶ exempts a physician from liability for civil damages for acts or omissions resulting
28 from the dispensing of an epinephrine auto-injector or stock albuterol under the
29 physician's standing prescription drug order;

30 ▶ exempts controlled substances dispensed for administration or use in a health care
31 facility outpatient setting from reporting to the state's controlled substance database;
32 and

33 ▶ makes technical and conforming changes.

34 **Money Appropriated in this Bill:**

35 None

36 **Other Special Clauses:**

37 This bill provides a special effective date.

38 **Utah Code Sections Affected:**

39 AMENDS:

40 **26-41-102 (Effective 07/01/20)**, as last amended by Laws of Utah 2019, Chapter 236

41 **26-41-105 (Effective 07/01/20)**, as last amended by Laws of Utah 2019, Chapter 236

42 **31A-46-102**, as enacted by Laws of Utah 2019, Chapter 241

43 **58-17b-605**, as last amended by Laws of Utah 2013, Chapter 423

44 **58-37f-201**, as last amended by Laws of Utah 2016, Chapter 99

45 **58-37f-203**, as last amended by Laws of Utah 2019, Chapter 59

46 ENACTS:

47 **58-17b-602.1**, Utah Code Annotated 1953

48 **58-17b-610.8**, Utah Code Annotated 1953

49 **58-17b-1001**, Utah Code Annotated 1953

50 **58-17b-1002**, Utah Code Annotated 1953

51 **58-17b-1003**, Utah Code Annotated 1953

52 **58-17b-1004**, Utah Code Annotated 1953

53 **58-17b-1005**, Utah Code Annotated 1953

54 **58-17b-1006**, Utah Code Annotated 1953

55 **58-17b-1007**, Utah Code Annotated 1953

56 RENUMBERS AND AMENDS:

57 **31A-46-305**, (Renumbered from 58-17b-619, as enacted by Laws of Utah 2004,

58 Chapter 280)

59 REPEALS AND REENACTS:

60 **58-17b-608**, as enacted by Laws of Utah 2004, Chapter 280

61

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

63 Section 1. Section **26-41-102 (Effective 07/01/20)** is amended to read:

64 **26-41-102 (Effective 07/01/20). Definitions.**

65 As used in this chapter:

66 (1) "Anaphylaxis" means a potentially life-threatening hypersensitivity to a substance.

67 (a) Symptoms of anaphylaxis may include shortness of breath, wheezing, difficulty
68 breathing, difficulty talking or swallowing, hives, itching, swelling, shock, or asthma.

69 (b) Causes of anaphylaxis may include insect sting, food allergy, drug reaction, and
70 exercise.

71 (2) "Asthma action plan" means a written plan:

72 (a) developed with a school nurse, a student's parent or guardian, and the student's
73 health care provider to help control the student's asthma; and

74 (b) signed by the student's:

75 (i) parent or guardian; and

76 (ii) health care provider.

77 (3) "Asthma emergency" means an episode of respiratory distress that may include
78 symptoms such as wheezing, shortness of breath, coughing, chest tightness, or breathing
79 difficulty.

80 (4) "Epinephrine auto-injector" means a portable, disposable drug delivery device that
81 contains a measured, single dose of epinephrine that is used to treat a person suffering a
82 potentially fatal anaphylactic reaction.

83 (5) "Health care provider" means an individual who is licensed as:

84 (a) a physician under Title 58, Chapter 67, Utah Medical Practice Act;

85 (b) a physician under Title 58, Chapter 68, Utah Osteopathic Medical Practice Act;

- 86 (c) an advanced practice registered nurse under Section [58-31b-302](#); or
- 87 (d) a physician assistant under Title 58, Chapter 70a, Utah Physician Assistant Act.
- 88 (6) "Pharmacist" means the same as that term is defined in Section [58-17b-102](#).
- 89 (7) "Pharmacy intern" means the same as that term is defined in Section [58-17b-102](#).
- 90 (8) "Physician" means the same as that term is defined in Section [58-67-102](#).
- 91 [~~6~~] (9) "Qualified adult" means a person who:
 - 92 (a) is 18 years of age or older; and
 - 93 (b) (i) for purposes of administering an epinephrine auto-injector, has successfully
 - 94 completed the training program established in Section [26-41-104](#); and
 - 95 (ii) for purposes of administering stock albuterol, has successfully completed the
 - 96 training program established in Section [26-41-104.1](#).
- 97 [~~7~~] (10) "Qualified epinephrine auto-injector entity":
 - 98 (a) means a facility or organization that employs, contracts with, or has a similar
 - 99 relationship with a qualified adult who is likely to have contact with another person who may
 - 100 experience anaphylaxis; and
 - 101 (b) includes:
 - 102 (i) recreation camps;
 - 103 (ii) an education facility, school, or university;
 - 104 (iii) a day care facility;
 - 105 (iv) youth sports leagues;
 - 106 (v) amusement parks;
 - 107 (vi) food establishments;
 - 108 (vii) places of employment; and
 - 109 (viii) recreation areas.
- 110 [~~8~~] (11) "Qualified stock albuterol entity" means a public or private school that
- 111 employs, contracts with, or has a similar relationship with a qualified adult who is likely to
- 112 have contact with another person who may experience an asthma emergency.
- 113 [~~9~~] (12) "Stock albuterol" means a prescription inhaled medication:

- 114 (a) used to treat asthma; and
- 115 (b) that may be delivered through a device, including:
- 116 (i) an inhaler; or
- 117 (ii) a nebulizer with a mouthpiece or mask.

118 Section 2. Section **26-41-105 (Effective 07/01/20)** is amended to read:

119 **26-41-105 (Effective 07/01/20). Authority to obtain and use an epinephrine**
120 **auto-injector or stock albuterol.**

121 (1) A qualified adult who is a teacher or other school employee at a public or private
122 primary or secondary school in the state, or a school nurse, may obtain from the school district
123 physician, the medical director of the local health department, or the local emergency medical
124 services director a prescription for:

- 125 (a) epinephrine auto-injectors for use in accordance with this chapter; or
- 126 (b) stock albuterol for use in accordance with this chapter.

127 ~~[(2) A qualified adult may obtain from a physician, pharmacist, or any other person or~~
128 ~~entity authorized to prescribe or dispense prescription drugs, a prescription for an epinephrine~~
129 ~~auto-injector or stock albuterol.]~~

130 (2) (a) A qualified adult may obtain an epinephrine auto-injector for use in accordance
131 with this chapter that is dispensed by:

- 132 (i) a pharmacist as provided under Section 58-17b-1004; or
- 133 (ii) a pharmacy intern as provided under Section 58-17b-1004.

134 (b) A qualified adult may obtain stock albuterol for use in accordance with this chapter
135 that is dispensed by:

- 136 (i) a pharmacist as provided under Section 58-17b-1004; or
- 137 (ii) a pharmacy intern as provided under Section 58-17b-1004.

138 (3) A qualified adult:

- 139 (a) may immediately administer an epinephrine auto-injector to a person exhibiting
140 potentially life-threatening symptoms of anaphylaxis when a physician is not immediately
141 available; and

142 (b) shall initiate emergency medical services or other appropriate medical follow-up in
143 accordance with the training materials retained under Section 26-41-104 after administering an
144 epinephrine auto-injector.

145 (4) If a school nurse is not immediately available, a qualified adult:

146 (a) may immediately administer stock albuterol to an individual who:

147 (i) has a diagnosis of asthma by a health care provider;

148 (ii) has a current asthma action plan on file with the school; and

149 (iii) is showing symptoms of an asthma emergency as described in the student's asthma
150 action plan; and

151 (b) shall initiate appropriate medical follow-up in accordance with the training
152 materials retained under Section 26-41-104.1 after administering stock albuterol.

153 (5) (a) A qualified entity that complies with Subsection (5)(b) or (c), may obtain [~~from~~
154 ~~a physician, pharmacist, or any other person authorized to prescribe or dispense prescription~~
155 ~~drugs, a prescription for]~~ a supply of epinephrine auto-injectors or stock albuterol, respectively,
156 from a pharmacist under Section 58-17b-1004, or a pharmacy intern under Section
157 58-17b-1004 for:

158 (i) storing:

159 (A) the epinephrine auto-injectors on the qualified epinephrine auto-injector entity's
160 premises; and

161 (B) stock albuterol on the qualified stock albuterol entity's premises; and

162 (ii) use by a qualified adult in accordance with Subsection (3) or (4).

163 (b) A qualified epinephrine auto-injector entity shall:

164 (i) designate an individual to complete an initial and annual refresher training program
165 regarding the proper storage and emergency use of an epinephrine auto-injector available to a
166 qualified adult; and

167 (ii) store epinephrine auto-injectors in accordance with the standards established by the
168 department in Section 26-41-107.

169 (c) A qualified stock albuterol entity shall:

170 (i) designate an individual to complete an initial and annual refresher training program
171 regarding the proper storage and emergency use of stock albuterol available to a qualified
172 adult; and

173 (ii) store stock albuterol in accordance with the standards established by the department
174 in Section [26-41-107](#).

175 Section 3. Section **31A-46-102** is amended to read:

176 **31A-46-102. Definitions.**

177 As used in this chapter:

178 (1) "Administrative fee" means any payment, other than a rebate, that a pharmaceutical
179 manufacturer makes directly or indirectly to a pharmacy benefit manager.

180 (2) "Contracting insurer" means an insurer as defined in Section [31A-22-636](#) with
181 whom a pharmacy benefit manager contracts to provide a pharmacy benefit management
182 service.

183 (3) "Device" means the same as that term is defined in Section [58-17b-102](#).

184 [~~3~~] (4) "Pharmacist" means the same as that term is defined in Section [58-17b-102](#).

185 [~~4~~] (5) "Pharmacy" means the same as that term is defined in Section [58-17b-102](#).

186 [~~5~~] (6) "Pharmacy benefits management service" means any of the following services
187 provided to a health benefit plan, or to a participant of a health benefit plan:

188 (a) negotiating the amount to be paid by a health benefit plan for a prescription drug; or

189 (b) administering or managing a prescription drug benefit provided by the health

190 benefit plan for the benefit of a participant of the health benefit plan, including administering
191 or managing:

192 (i) a mail service pharmacy;

193 (ii) a specialty pharmacy;

194 (iii) claims processing;

195 (iv) payment of a claim;

196 (v) retail network management;

197 (vi) clinical formulary development;

198 (vii) clinical formulary management services;
 199 (viii) rebate contracting;
 200 (ix) rebate administration;
 201 (x) a participant compliance program;
 202 (xi) a therapeutic intervention program;
 203 (xii) a disease management program; or
 204 (xiii) a service that is similar to, or related to, a service described in Subsection [~~(5)~~]
 205 ~~(6)~~(a) or [~~(5)~~] ~~(6)~~(b)(i) through (xii).

206 [~~(6)~~] (7) "Pharmacy benefit manager" means a person licensed under this chapter to
 207 provide a pharmacy benefits management service.

208 [~~(7)~~] (8) "Pharmacy service" means a product, good, or service provided to an
 209 individual by a pharmacy or pharmacist.

210 [~~(8)~~] (9) (a) "Rebate" means a refund, discount, or other price concession that is paid
 211 by a pharmaceutical manufacturer to a pharmacy benefit manager based on a prescription
 212 drug's utilization or effectiveness.

213 (b) "Rebate" does not include an administrative fee.

214 Section 4. Section **31A-46-305**, which is renumbered from Section 58-17b-619 is
 215 renumbered and amended to read:

216 [~~58-17b-619~~]. **31A-46-305. Out-of-state mail service pharmacies -- Drugs**
 217 **not readily available in all pharmacies.**

218 (1) As used in this section, "out-of-state mail service pharmacy" means the same as that
 219 term is defined in Section [58-17b-102](#).

220 [~~(1) Any~~] (2) Except as provided in Subsection (3), a third party payor [for] of
 221 pharmaceutical services within the state, or its agent or contractor, may not require [any] a
 222 pharmacy patient to obtain prescription drug benefits from [a specific] one or more out-of-state
 223 [pharmacy] mail service pharmacies as a condition of obtaining third party payment
 224 prescription drug benefit coverage as defined in rule.

225 [~~(2) (a) This section does not prohibit any third party payor of pharmaceutical services;~~

226 who provides for reimbursement to the pharmacy patient or payment on his behalf, from
227 exercising the right to limit the amount reimbursed for the cost of prescription drugs based
228 upon the cost of identical prescription drugs available through a designated out-of-state
229 pharmacy.]

230 [~~(b) Notwithstanding Subsection (2)(a), any third party payor of pharmaceutical~~
231 ~~services may restrict the type of outlet where a patient may obtain certain prescriptive drugs~~
232 ~~and devices, such as injectable medications, that are not readily available in all pharmacies.~~
233 ~~The payor may also restrict access to no more than one mail-order pharmacy.]~~

234 [~~(3) Each third party payor of pharmaceutical services shall identify as a part of the~~
235 ~~third party agreement or contract the designated out-of-state pharmacy which shall be used as~~
236 ~~the base line comparison.]~~

237 (3) For a prescription drug or device that is not readily available in all pharmacies,
238 including an injectable medication, a third party payor of pharmaceutical services may require a
239 pharmacy patient to obtain prescription drug benefits from certain pharmacies, including one or
240 more out-of-state mail service pharmacies.

241 (4) (a) A violation of this section is a class A misdemeanor.

242 (b) Each violation of this section is a separate offense.

243 Section 5. Section **58-17b-602.1** is enacted to read:

244 **58-17b-602.1. Dispensing quantity or dosage form different from prescription.**

245 (1) Without specific authorization from a prescriber, a pharmacist or pharmacy intern
246 may dispense:

247 (a) a prescription in a quantity different than the quantity prescribed if the prescribed
248 quantity or package size is not commercially available; and

249 (b) a prescription in a dosage form different than the dosage form prescribed, if in the
250 professional judgement of the pharmacist or pharmacy intern, dispensing a different dosage
251 form is in the best interest of the patient.

252 (2) This section does not apply if:

253 (a) the substitute would change the bioavailability of the medication;

254 (b) the substitute would change the treatment parameters; or

255 (c) the prescriber has written or clearly designated "dispense as written" on the
256 prescription.

257 Section 6. Section **58-17b-605** is amended to read:

258 **58-17b-605. Drug product equivalents.**

259 (1) For the purposes of this section:

260 (a) (i) "Drug" is as defined in Section [58-17b-102](#).

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

262 (b) "Drug product equivalent" means:

263 (i) a drug product that is designated as the therapeutic equivalent of another drug
264 product in the Approved Drug Products with Therapeutic Equivalence Evaluations prepared by
265 the Center for Drug Evaluation and Research of the United States Food and Drug
266 Administration[-]; and

267 (ii) notwithstanding Subsection (1)(b)(i), an appropriate substitute for albuterol
268 designated by division rule made under Subsection (9).

269 (2) A pharmacist or pharmacy intern dispensing a prescription order for a specific drug
270 by brand or proprietary name may substitute a drug product equivalent for the prescribed drug
271 only if:

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

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

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

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

282 (e) the prescribing practitioner has not indicated that a drug product equivalent may not
283 be substituted for the drug, as provided in Subsection (6); and

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

285 (3) (a) Each out-of-state mail service pharmacy dispensing a drug product equivalent as
286 a substitute for another drug into this state shall notify the patient of the substitution either by
287 telephone or in writing.

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

291 (4) Pharmacists or pharmacy interns may not substitute without the prescriber's
292 authorization on trade name drug product prescriptions unless the product is currently
293 categorized in the approved drug products with therapeutic equivalence evaluations prepared
294 by the Center for Drug Evaluation and Research of the Federal Food and Drug Administration
295 as a drug product considered to be therapeutically equivalent to another drug product.

296 (5) A pharmacist or pharmacy intern who dispenses a prescription with a drug product
297 equivalent under this section assumes no greater liability than would be incurred had the
298 pharmacist or pharmacy intern dispensed the prescription with the drug product prescribed.

299 (6) (a) If, in the opinion of the prescribing practitioner, it is in the best interest of the
300 patient that a drug product equivalent not be substituted for a prescribed drug, the practitioner
301 may indicate a prohibition on substitution either by writing "dispense as written" or signing in
302 the appropriate space where two lines have been preprinted on a prescription order and
303 captioned "dispense as written" or "substitution permitted".

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

309 (7) A pharmacist or pharmacy intern who substitutes a drug product equivalent for a

310 prescribed drug shall communicate the substitution to the purchaser. The drug product
311 equivalent container shall be labeled with the name of the drug dispensed, and the pharmacist,
312 pharmacy intern, or pharmacy technician shall indicate on the file copy of the prescription both
313 the name of the prescribed drug and the name of the drug product equivalent dispensed in its
314 place.

315 (8) (a) For purposes of this Subsection (8), "substitutes" means to substitute:

- 316 (i) a generic drug for another generic drug;
317 (ii) a generic drug for a nongeneric drug;
318 (iii) a nongeneric drug for another nongeneric drug; or
319 (iv) a nongeneric drug for a generic drug.

320 (b) A prescribing practitioner who makes a finding under Subsection (6)(a) for a
321 patient with a seizure disorder shall indicate a prohibition on substitution of a drug product
322 equivalent in the manner provided in Subsection (6)(a) or (b).

323 (c) Except as provided in Subsection (8)(d), a pharmacist or pharmacy intern who
324 cannot dispense the prescribed drug as written, and who needs to substitute a drug product
325 equivalent for the drug prescribed to the patient to treat or prevent seizures shall notify the
326 prescribing practitioner prior to the substitution.

327 (d) Notification under Subsection (8)(c) is not required if the drug product equivalent is
328 paid for in whole or in part by Medicaid.

329 (9) (a) The division shall designate by rule made in accordance with Title 63G, Chapter
330 3, Utah Administrative Rulemaking Act, and in consultation with the board, the Physicians
331 Licensing Board created in Section 58-67-201, and the Osteopathic Physician and Surgeon's
332 Licensing Board created in Section 58-68-201, appropriate substitutes for albuterol.

333 (b) Subsections (2)(b) and (4) do not apply to the substitution of a drug product
334 equivalent for albuterol.

335 ~~[(9)]~~ (10) Failure of a licensed medical practitioner to specify that no substitution is
336 authorized does not constitute evidence of negligence.

337 Section 7. Section **58-17b-608** is repealed and reenacted to read:

338 58-17b-608. Emergency refills.

339 (1) If a prescription may not be refilled otherwise, a pharmacist or pharmacy intern
340 may refill the prescription in an emergency without the prescribing practitioner's authorization
341 if:

342 (a) the prescription is for a drug that is not a controlled substance;

343 (b) the patient is currently using the drug prescribed;

344 (c) the prescribing practitioner is not available promptly to authorize the refill;

345 (d) the pharmacist or pharmacy intern, or another pharmacist or pharmacy intern at the
346 same pharmacy, has not previously dispensed a refill for the prescription under this section;

347 (e) refilling the prescription is in the interest of the patient's health;

348 (f) in the professional judgment of the pharmacist or pharmacy intern the prescription
349 should be refilled;

350 (g) except as provided in Subsection (1)(h), the pharmacist or pharmacy intern
351 dispenses the medication in accordance with the prescribing practitioner's instructions included
352 with the prescription; and

353 (h) the pharmacist or pharmacy intern dispenses no more than the amount necessary to
354 address the emergency.

355 (2) If the prescription for a drug dispensed under Subsection (1) is on file with the
356 pharmacy where the drug is dispensed, the pharmacist or pharmacy intern may dispense more
357 than a three-day supply only if:

358 (a) (i) the prescription has expired within the past 30 days; or

359 (ii) no refills are remaining on the prescription; and

360 (b) the amount dispensed does not exceed the lesser of:

361 (i) a 30-day supply; or

362 (ii) the quantity last dispensed at the pharmacy pursuant to the prescription as either a
363 fill or a refill.

364 (3) A pharmacist or pharmacy intern who dispenses a prescription refill under this
365 section shall inform the prescribing practitioner of the emergency refill as soon as practicable.

366 Section 8. Section **58-17b-610.8** is enacted to read:

367 **58-17b-610.8. Prescription devices.**

368 (1) The following documents from a prescribing practitioner shall be considered a
369 prescription for purposes of dispensing of and payment for a device described in Subsection
370 (3), if the device is prescribed or indicated by the document and the document is on file with a
371 pharmacy:

372 (a) a written prescription; or

373 (b) a written record of a patient's:

374 (i) current diagnosis; or

375 (ii) treatment protocol.

376 (2) A pharmacist or pharmacy intern at a pharmacy at which a document that is
377 considered a prescription under Subsection (1) is on file may dispense a prescription device
378 described in Subsection (3) to the patient in accordance with:

379 (a) the document that is considered a prescription under Subsection (1); and

380 (b) rules made by the division under Subsection (4).

381 (3) This section applies to:

382 (a) nebulizers;

383 (b) spacers for use with nebulizers or inhalers; and

384 (c) diabetic testing supplies.

385 (4) The division shall make rules in accordance with Title 63G, Chapter 3, Utah
386 Administrative Rulemaking Act, and in consultation with the board, the Physicians Licensing
387 Board created in Section [58-67-201](#), and the Osteopathic Physician and Surgeon's Licensing
388 Board created in Section [58-68-201](#), to implement this section.

389 Section 9. Section **58-17b-1001** is enacted to read:

390 **Part 10. Epinephrine Auto-Injector and Stock Albuterol Act**

391 **58-17b-1001. Title.**

392 This part is known as the "Epinephrine Auto-Injector and Stock Albuterol Act."

393 Section 10. Section **58-17b-1002** is enacted to read:

394 **58-17b-1002. Definitions.**

395 As used in this part:

396 (1) "Epinephrine auto-injector" means the same as that term is defined in Section
397 26-41-102.

398 (2) "Local health department" means the same as that term is defined in Section
399 26A-1-102.

400 (3) "Physician" means the same as that term is defined in Section 58-67-102.

401 (4) "Qualified adult" means the same as that term is defined in Section 26-41-102.

402 (5) "Qualified epinephrine auto-injector entity" means the same as that term is defined
403 in Section 26-41-102.

404 (6) "Qualified stock albuterol entity" means the same as that term is defined in Section
405 26-41-102.

406 (7) "Stock albuterol" means the same as that term is defined in Section 26-41-102.

407 Section 11. Section **58-17b-1003** is enacted to read:

408 **58-17b-1003. Voluntary participation.**

409 This part does not create a duty or standard of care for a person to prescribe or dispense
410 an epinephrine auto-injector or stock albuterol.

411 Section 12. Section **58-17b-1004** is enacted to read:

412 **58-17b-1004. Authorization to dispense an epinephrine auto-injector and stock**
413 **albuterol pursuant to a standing order.**

414 (1) Notwithstanding any other provision of this chapter, a pharmacist or pharmacy
415 intern may dispense an epinephrine auto-injector:

416 (a) (i) to a qualified adult for use in accordance with Title 26, Chapter 41, Emergency
417 Response for Life-threatening Conditions; or

418 (ii) to a qualified epinephrine auto-injector entity for use in accordance with Title 26,
419 Chapter 41, Emergency Response for Life-threatening Conditions;

420 (b) pursuant to a standing prescription drug order made in accordance with Section
421 58-17b-1005;

422 (c) without any other prescription drug order from a person licensed to prescribe an
423 epinephrine auto-injector; and

424 (d) in accordance with the dispensing guidelines in Section 58-17b-1006.

425 (2) Notwithstanding any other provision of this chapter, a pharmacist or pharmacist
426 intern may dispense stock albuterol:

427 (a) (i) to a qualified adult for use in accordance with Title 26, Chapter 41, Emergency
428 Response for Life-threatening Conditions; or

429 (ii) to a qualified stock albuterol entity for use in accordance with Title 26, Chapter 41,
430 Emergency Response for Life-threatening Conditions;

431 (b) pursuant to a standing prescription drug order made in accordance with Section
432 58-17b-1005;

433 (c) without any other prescription drug order from a person licensed to prescribe stock
434 albuterol; and

435 (d) in accordance with the dispensing guidelines in Section 58-17b-1006.

436 Section 13. Section **58-17b-1005** is enacted to read:

437 **58-17b-1005. Standing prescription drug orders for epinephrine auto-injectors**
438 **and stock albuterol.**

439 (1) A physician acting in the physician's capacity as an employee of the Department of
440 Health or as a medical director of a local health department may issue a standing prescription
441 drug order authorizing the dispensing of an epinephrine auto-injector under Section
442 58-17b-1004 in accordance with a protocol that:

443 (a) requires the physician to specify the persons, by professional license number,
444 authorized to dispense the epinephrine auto-injector;

445 (b) requires the physician to review at least annually the dispensing practices of those
446 authorized by the physician to dispense the epinephrine auto-injector;

447 (c) requires those authorized by the physician to dispense the epinephrine auto-injector
448 to make and retain a record of each dispensing, including:

449 (i) the name of the qualified adult or qualified epinephrine auto-injector entity to whom

450 the epinephrine auto-injector is dispensed;

451 (ii) a description of the epinephrine auto-injector dispensed; and

452 (iii) other relevant information; and

453 (d) is approved by the division by administrative rule made in accordance with Title

454 63G, Chapter 3, Utah Administrative Rulemaking Act, in collaboration with the Physicians

455 Licensing Board created in Section [58-67-201](#) and the Board of Pharmacy.

456 (2) A physician acting in the physician's capacity as an employee of the Department of

457 Health or as a medical director of a local health department may issue a standing prescription

458 drug order authorizing the dispensing of the stock albuterol under Section [58-17b-1004](#) in

459 accordance with a protocol that:

460 (a) requires the physician to specify the persons, by professional license number,

461 authorized to dispense the stock albuterol;

462 (b) requires the physician to review at least annually the dispensing practices of those

463 authorized by the physician to dispense the stock albuterol;

464 (c) requires those authorized by the physician to dispense the stock albuterol to make

465 and retain a record of each dispensing, including:

466 (i) the name of the qualified adult or qualified stock albuterol entity to whom the stock

467 albuterol is dispensed;

468 (ii) a description of the stock albuterol dispensed; and

469 (iii) other relevant information; and

470 (d) is approved by the division by administrative rule made in accordance with Title

471 63G, Chapter 3, Utah Administrative Rulemaking Act, in collaboration with the Physicians

472 Licensing Board created in Section [58-67-201](#) and the board.

473 Section 14. Section **58-17b-1006** is enacted to read:

474 **58-17b-1006. Guidelines for dispensing an epinephrine auto-injector and stock**

475 **albuterol.**

476 (1) A pharmacist or pharmacy intern who dispenses an epinephrine auto-injector under

477 this part shall, at a minimum, provide patient counseling to the qualified adult or qualified

478 epinephrine auto-injector entity to whom the epinephrine auto-injector is dispensed regarding:

479 (a) the appropriate administration and storage of the epinephrine auto-injector;

480 (b) potential side effects and risks of the epinephrine auto-injector; and

481 (c) when to seek emergency medical attention.

482 (2) A pharmacist or pharmacy intern who dispenses stock albuterol under this part

483 shall, at a minimum, provide patient counseling to the qualified adult or qualified stock

484 albuterol entity to whom the stock albuterol is dispensed regarding:

485 (a) the appropriate administration and storage of the stock albuterol;

486 (b) potential side effects and risks of the stock albuterol; and

487 (c) when to seek emergency medical attention.

488 Section 15. Section **58-17b-1007** is enacted to read:

489 **58-17b-1007. Limited civil liability.**

490 (1) A physician who issues a standing prescription drug order in accordance with
491 Subsection [58-17b-1005](#)(1) is not liable for any civil damages for acts or omissions resulting
492 from the dispensing of an epinephrine auto-injector under this part.

493 (2) A physician who issues a standing prescription drug order in accordance with
494 Subsection [58-17b-1005](#)(2) is not liable for any civil damages for acts or omissions resulting
495 from the dispensing of stock albuterol under this part.

496 Section 16. Section **58-37f-201** is amended to read:

497 **58-37f-201. Controlled substance database -- Creation -- Purpose.**

498 (1) There is created within the division a controlled substance database.

499 (2) The division shall administer and direct the functioning of the database in
500 accordance with this chapter.

501 (3) The division may, under state procurement laws, contract with another state agency
502 or a private entity to establish, operate, or maintain the database.

503 (4) The division shall, in collaboration with the board, determine whether to operate
504 the database within the division or contract with another entity to operate the database, based
505 on an analysis of costs and benefits.

- 506 (5) The purpose of the database is to contain:
- 507 (a) the data described in Section 58-37f-203 regarding ~~[every prescription for a~~
508 ~~controlled substance dispensed in the state to any individual other than an inpatient in a~~
509 ~~licensed health care facility]~~ prescriptions for dispensed controlled substances;
- 510 (b) data reported to the division under Section 26-21-26 regarding poisoning or
511 overdose;
- 512 (c) data reported to the division under Subsection 41-6a-502(4) or 41-6a-502.5(5)(b)
513 regarding convictions for driving under the influence of a prescribed controlled substance or
514 impaired driving; and
- 515 (d) data reported to the division under Subsection 58-37-8(1)(e) or 58-37-8(2)(j)
516 regarding certain violations of the Utah Controlled Substances Act.
- 517 (6) The division shall maintain the database in an electronic file or by other means
518 established by the division to facilitate use of the database for identification of:
- 519 (a) prescribing practices and patterns of prescribing and dispensing controlled
520 substances;
- 521 (b) practitioners prescribing controlled substances in an unprofessional or unlawful
522 manner;
- 523 (c) individuals receiving prescriptions for controlled substances from licensed
524 practitioners, and who subsequently obtain dispensed controlled substances from a drug outlet
525 in quantities or with a frequency inconsistent with generally recognized standards of dosage for
526 that controlled substance;
- 527 (d) individuals presenting forged or otherwise false or altered prescriptions for
528 controlled substances to a pharmacy;
- 529 (e) individuals admitted to a general acute hospital for poisoning or overdose involving
530 a prescribed controlled substance; and
- 531 (f) individuals convicted for:
- 532 (i) driving under the influence of a prescribed controlled substance that renders the
533 individual incapable of safely operating a vehicle;

534 (ii) driving while impaired, in whole or in part, by a prescribed controlled substance; or
535 (iii) certain violations of the Utah Controlled Substances Act.

536 Section 17. Section **58-37f-203** is amended to read:

537 **58-37f-203. Submission, collection, and maintenance of data.**

538 (1) (a) The division shall implement on a statewide basis, including non-resident
539 pharmacies as defined in Section **58-17b-102**, the following two options for a pharmacist to
540 submit information:

541 (i) real-time submission of the information required to be submitted under this part to
542 the controlled substance database; and

543 (ii) 24-hour daily or next business day, whichever is later, batch submission of the
544 information required to be submitted under this part to the controlled substance database.

545 (b) (i) On and after January 1, 2016, a pharmacist shall comply with either:

546 (A) the submission time requirements established by the division under Subsection
547 (1)(a)(i); or

548 (B) the submission time requirements established by the division under Subsection
549 (1)(a)(ii).

550 (ii) Prior to January 1, 2016, a pharmacist may submit information using either option
551 under this Subsection (1).

552 (c) The division shall comply with Title 63G, Chapter 6a, Utah Procurement Code.

553 (2) (a) The pharmacist-in-charge and the pharmacist of the drug outlet where a
554 controlled substance is dispensed shall submit the data described in this section to the division
555 in accordance with:

556 (i) the requirements of this section;

557 (ii) the procedures established by the division;

558 (iii) additional types of information or data fields established by the division; and

559 (iv) the format established by the division.

560 (b) A dispensing medical practitioner licensed under Chapter 17b, Part 8, Dispensing
561 Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy, shall comply with

562 the provisions of this section and the dispensing medical practitioner shall assume the duties of
563 the pharmacist under this chapter.

564 (3) (a) ~~[The]~~ Except as provided in Subsection (3)(b), the pharmacist-in-charge and the
565 pharmacist described in Subsection (2)(b) shall, for each controlled substance dispensed by a
566 pharmacist under the pharmacist's supervision [other than those dispensed for an inpatient at a
567 health care facility], submit to the division any type of information or data field established by
568 the division by rule in accordance with Subsection (6) regarding:

569 (i) each controlled substance that is dispensed by the pharmacist or under the
570 pharmacist's supervision; and

571 (ii) each noncontrolled substance that is:

572 (A) designated by the division under Subsection (8)(a); and

573 (B) dispensed by the pharmacist or under the pharmacist's supervision.

574 (b) Subsection (3)(a) does not apply to a drug that is dispensed for ~~[an inpatient]~~
575 administration to, or use by, a patient at a health care facility, including a patient in an
576 outpatient setting at the health care facility.

577 (4) An individual whose records are in the database may obtain those records upon
578 submission of a written request to the division.

579 (5) (a) A patient whose record is in the database may contact the division in writing to
580 request correction of any of the patient's database information that is incorrect. The patient
581 shall provide a postal address for the division's response.

582 (b) The division shall grant or deny the request within 30 days from receipt of the
583 request and shall advise the requesting patient of its decision by mail postmarked within 35
584 days of receipt of the request.

585 (c) If the division denies a request under this Subsection (5) or does not respond within
586 35 days, the patient may submit an appeal to the Department of Commerce, within 60 days
587 after the postmark date of the patient's letter making a request for a correction under this
588 Subsection (5).

589 (6) The division shall make rules, in accordance with Title 63G, Chapter 3, Utah

590 Administrative Rulemaking Act, to establish submission requirements under this part,
591 including:

- 592 (a) electronic format;
- 593 (b) submission procedures; and
- 594 (c) required information and data fields.

595 (7) The division shall ensure that the database system records and maintains for
596 reference:

- 597 (a) the identification of each individual who requests or receives information from the
598 database;
- 599 (b) the information provided to each individual; and
- 600 (c) the date and time that the information is requested or provided.

601 (8) (a) The division, in collaboration with the Utah Controlled Substance Advisory
602 Committee created in Section [58-38a-201](#), shall designate a list of noncontrolled substances
603 described in Subsection (8)(b) by rule made in accordance with Title 63G, Chapter 3, Utah
604 Administrative Rulemaking Act.

605 (b) To determine whether a prescription drug should be designated in the schedules of
606 controlled substances under this chapter, the division may collect information about a
607 prescription drug as defined in Section [58-17b-102](#) that is not designated in the schedules of
608 controlled substances under this chapter.

609 Section 18. **Effective date.**

610 (1) Except as provided in Subsection (2), this bill takes effect on May 12, 2020.

611 (2) The actions affecting the following sections take effect on July 1, 2020:

- 612 (a) Section [26-41-102](#);
- 613 (b) Section [26-41-105](#);
- 614 (c) Section [58-17b-1001](#);
- 615 (d) Section [58-17b-1002](#);
- 616 (e) Section [58-17b-1003](#);
- 617 (f) Section [58-17b-1004](#);

- 618 (g) Section 58-17b-1005;
- 619 (h) Section 58-17b-1006; and
- 620 (i) Section 58-17b-1007.