Senator Evan J. Vickers proposes the following substitute bill:

1	PHARMACY PRACTICE ACT AMENDMENTS
2	2020 GENERAL SESSION
3	STATE OF UTAH
4	Chief Sponsor: Evan J. Vickers
5	House Sponsor: Suzanne Harrison
6 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	 authorizes the dispensing of a quantity or dosage form different from a prescription
16	in certain instances;
17	 amends provisions related to the dispensing of a substitute for albuterol;
18	amends provisions relating to emergency refills;
19	 authorizes the dispensing of certain prescription medical devices without a
20	prescription;
21	► authorizes $\hat{S} \rightarrow [a \text{ physician}]$ <u>certain physicians</u> $\leftarrow \hat{S}$ to issue a standing prescription drug
21a	order for an epinephrine
22	auto-injector or stock albuterol in accordance with a protocol that meets certain
23	requirements;
24	 exempts a physician from liability for civil damages for acts or omissions resulting
25	from the dispensing of an epinephrine auto-injector or stock albuterol under the



119	(b) stock albuterol for use in accordance with this chapter.
120	[(2) A qualified adult may obtain from a physician, pharmacist, or any other person or
121	entity authorized to prescribe or dispense prescription drugs, a prescription for an epinephrine
122	auto-injector or stock albuterol.]
123	(2) (a) A qualified adult may obtain an epinephrine auto-injector for use in accordance
124	with this chapter that is \$→ [dispersed] dispensed ←\$ by:
125	(i) a pharmacist as provided under Section 58-17b-1004; or
126	(ii) a pharmacy intern as provided under Section 58-17b-1004.
127	(b) A qualified adult may obtain stock albuterol for use in accordance with this chapter
128	that is $\hat{S} \rightarrow [\underline{dispersed}]$ dispensed $\leftarrow \hat{S}$ by:
129	(i) a pharmacist as provided under Section 58-17b-1004; or
130	(ii) a pharmacy intern as provided under Section 58-17b-1004.
131	(3) A qualified adult:
132	(a) may immediately administer an epinephrine auto-injector to a person exhibiting
133	potentially life-threatening symptoms of anaphylaxis when a physician is not immediately
134	available; and
135	(b) shall initiate emergency medical services or other appropriate medical follow-up in
136	accordance with the training materials retained under Section 26-41-104 after administering an
137	epinephrine auto-injector.
138	(4) If a school nurse is not immediately available, a qualified adult:
139	(a) may immediately administer stock albuterol to an individual who:
140	(i) has a diagnosis of asthma by a health care provider;
141	(ii) has a current asthma action plan on file with the school; and
142	(iii) is showing symptoms of an asthma emergency as described in the student's asthma
143	action plan; and
144	(b) shall initiate appropriate medical follow-up in accordance with the training
145	materials retained under Section 26-41-104.1 after administering stock albuterol.
146	(5) (a) A qualified entity that complies with Subsection (5)(b) or (c), may obtain [from
147	a physician, pharmacist, or any other person authorized to prescribe or dispense prescription
148	drugs, a prescription for] a supply of epinephrine auto-injectors or stock albuterol, respectively,
149	from a pharmacist under Section 58-17b-1004, or a pharmacy intern under Section

150	<u>58-1/b-1004</u> for:
151	(i) storing:
152	(A) the epinephrine auto-injectors on the qualified epinephrine auto-injector entity's
153	premises; and
154	(B) stock albuterol on the qualified stock albuterol entity's premises; and
155	(ii) use by a qualified adult in accordance with Subsection (3) or (4).
156	(b) A qualified epinephrine auto-injector entity shall:
157	(i) designate an individual to complete an initial and annual refresher training program
158	regarding the proper storage and emergency use of an epinephrine auto-injector available to a
159	qualified adult; and
160	(ii) store epinephrine auto-injectors in accordance with the standards established by the
161	department in Section 26-41-107.
162	(c) A qualified stock albuterol entity shall:
163	(i) designate an individual to complete an initial and annual refresher training program
164	regarding the proper storage and emergency use of stock albuterol available to a qualified
165	adult; and
166	(ii) store stock albuterol in accordance with the standards established by the department
167	in Section 26-41-107.
168	Section 3. Section 58-17b-602.1 is enacted to read:
169	58-17b-602.1. Dispensing quantity or dosage form different from prescription.
170	(1) Without specific authorization from a prescriber, a pharmacist or pharmacy intern
171	may dispense:
172	(a) a prescription in a quantity different than the quantity prescribed if the prescribed
173	quantity or package size is not commercially available; and
174	(b) a prescription in a dosage form different than the dosage form prescribed $\hat{S} \rightarrow , \leftarrow \hat{S}$ if in
174a	<u>the</u>
175	professional judgement of the pharmacist or pharmacy intern \$→, ←\$ dispensing a different
175a	dosage
176	form is in the best interest of the patient.
177	(2) This section does not apply if:
178	(a) the substitute would change the bioavailability of the medication;
179	(b) the substitute would change the treatment parameters; or
180	(c) the prescriber has written or clearly designated "dispense as written" on the

243	(iii) a nongeneric drug for another nongeneric drug; or
244	(iv) a nongeneric drug for a generic drug.
245	(b) A prescribing practitioner who makes a finding under Subsection (6)(a) for a
246	patient with a seizure disorder shall indicate a prohibition on substitution of a drug product
247	equivalent in the manner provided in Subsection (6)(a) or (b).
248	(c) Except as provided in Subsection (8)(d), a pharmacist or pharmacy intern who
249	cannot dispense the prescribed drug as written, and who needs to substitute a drug product
250	equivalent for the drug prescribed to the patient to treat or prevent seizures shall notify the
251	prescribing practitioner prior to the substitution.
252	(d) Notification under Subsection (8)(c) is not required if the drug product equivalent is
253	paid for in whole or in part by Medicaid.
254	(9) (a) The division shall designate by rule made in accordance with Title 63G, Chapter
255	3, Utah Administrative Rulemaking Act, and in consultation with the board, the Physicians
256	Licensing Board created in Section 58-67-201, and the Osteopathic Physician and Surgeon's
257	Licensing Board created in Section 58-68-201, appropriate substitutes for albuterol.
258	(b) Subsections (2)(b) and (4) do not apply to the substitution of a drug product
259	equivalent for albuterol.
260	[(9)] (10) Failure of a licensed medical practitioner to specify that no substitution is
261	authorized does not constitute evidence of negligence.
262	Section 5. Section 58-17b-608 is repealed and reenacted to read:
263	58-17b-608. Emergency refills.
264	(1) If a prescription may not $\$ \rightarrow [\underline{\text{otherwise}}] \leftarrow \$$ be refilled $\$ \rightarrow \underline{\text{otherwise}} \leftarrow \$$, a
264a	pharmacist or pharmacy intern
265	may refill the prescription in an emergency without the prescribing practitioner's authorization
266	<u>if:</u>
267	(a) the prescription is for a drug that is not a controlled substance;
268	(b) the patient is currently using the drug prescribed;
269	(c) the prescribing practitioner is not available promptly to authorize the refill;
270	(d) the pharmacist or pharmacy intern, or another pharmacist or pharmacy $\hat{S} \rightarrow [inter]$
270a	<u>intern</u> ←Ŝ <u>at the</u>
271	same pharmacy, has not previously dispensed a refill for the prescription under this section;
272	(e) refilling the prescription is in the interest of the patient's health;
273	(f) in the professional judgment of the pharmacist or pharmacy intern the prescription

2/4	should be refilled;
275	(g) except as provided in Subsection (1)(h), the pharmacist or pharmacy intern
276	dispenses the medication in accordance with the prescribing practitioner's instructions included
277	with the prescription; and
278	(h) the pharmacist or pharmacy intern dispenses no more than the amount necessary to
279	address the emergency.
280	(2) If the prescription for a drug dispensed under Subsection (1) is on file with the
281	pharmacy where the drug is dispensed, the pharmacist or pharmacy intern may dispense more
282	than a three-day supply only if:
283	(a) (i) the prescription has expired within the past 30 days; or
284	(ii) no refills are remaining on the prescription; and
285	(b) the amount dispensed does not exceed the lesser of:
286	(i) a 30-day supply; or
287	(ii) the quantity last dispensed at the pharmacy pursuant to the prescription as either a
288	fill or a refill \$→ [; and]. ←\$
289	(3) A pharmacist or pharmacy intern who dispenses a prescription refill under this
290	section shall inform the prescribing practitioner of the emergency refill as soon as practicable.
291	Section 6. Section 58-17b-610.8 is enacted to read:
292	58-17b-610.8. Prescription devices.
293	$\hat{\mathbf{H}} \Rightarrow [\underline{(1)} \ \ \mathbf{A} \ \ \mathbf{pharmacist} \ \ \mathbf{or} \ \ \mathbf{pharmacy} \ \ \mathbf{intern} \ \ \mathbf{may} \ \ \mathbf{prescribe} \ \ \mathbf{and} \ \ \mathbf{dispense} \ \ \mathbf{a} \ \ \mathbf{prescription} \ \ \mathbf{device}$
294	described in Subsection (2) to a patient if:
295	(a) the patient has a current diagnosis, prescription, or treatment protocol from a
296	prescribing practitioner for which one or more of the devices described in Subsection (2) is
297	indicated; and
298	(b) the pharmacist or pharmacy intern acts in accordance with rules made by the
299	division under Subsection (3).
300	(2) This section applies to:
301	(a) nebulizers;
302	(b) spacers for use with nebulizers or inhalers; and
303	(c) diabetic testing supplies.
304	(3) The division shall make rules in accordance with Title 63G, Chapter 3, Utah]

305	Ĥ→ [Administrative Rulemaking Act, and in consultation with the board, the Physicians Licensing
306	Board created in Section 58-67-201, and the Osteopathic Physician and Surgeon's Licensing
307	Board created in Section 58-68-201, to implement this section.
307a	(1) Any of the following documents from a prescribing practitioner shall be considered
307b	a prescription for purposes of the dispensing of and payment for a device described in
307c	Subsection (3), if the device is prescribed or indicated by the document and the document is on
307d	file with a pharmacy:
307e	(a) a written prescription; or
307f	(b) a written record of a patient's:
307g	(i) current diagnosis; or
307h	(ii) treatment protocol.
307i	(2) A pharmacist or pharmacy intern at a pharmacy at which a document considered a
307j	prescription in Subsection (1) is on file may dispense a prescription device described in
307k	Subsection (3) to the patient in accordance with:
3071	(a) the document; and
307m	(b) rules made by the division under Subsection (4).
307n	(3) This section applies to:
307o	(a) nebulizers;
307p	(b) spacers for use with nebulizers or inhalers; and
307q	(c) diabetic testing supplies.
307r	(4) The division shall make rules in accordance with Title 63G, Chapter 3, Utah
307s	Administrative Rulemaking Act, and in consultation with the board, the Physicians Licensing
307t	Board created in Section 58-67-201, and the Osteopathic Physician and Surgeon's Licensing
307u	Board created in Section 58-68-201, to implement this section. ←Ĥ
308	Section 7. Section 58-17b-1001 is enacted to read:
309	Part 10. Epinephrine Auto-Injector and Stock Albuterol Act
310	<u>58-17b-1001.</u> Title.
311	This part is known as the "Epinephrine Auto-Injector and Stock Albuterol Act."
312	Section 8. Section 58-17b-1002 is enacted to read:
313	<u>58-17b-1002.</u> Definitions.
314	As used in this part:
315	(1) "Epinephrine auto-injector" means the same as that term is defined in Section
316	<u>26-41-102.</u>
317	(2) "Local health department" means the same as that term is defined in Section

318	2 26A-1-102.
319	(3) "Physician" means the same as that term is defined in Section 58-10-102.
320	(4) "Qualified adult" means the same as that term is defined in Section 26-41-102.
321	(5) "Qualified epinephrine auto-injector entity" means the same as that term is defined
322	<u>in Section 26-41-102.</u>
323	(6) "Qualified stock albuterol entity" means the same as that term is defined in Section
324	<u>26-41-102.</u>
325	(7) "Stock albuterol" means the same as that term is defined in Section 26-41-102.
326	Section 9. Section 58-17b-1003 is enacted to read:
327	58-17b-1003. Voluntary participation.
328	This part does not create a duty or standard of care for a person to prescribe or dispense
329	an epinephrine auto-injector or stock albuterol.
330	Section 10. Section 58-17b-1004 is enacted to read:
331	58-17b-1004. Authorization to dispense an epinephrine auto-injector and stock
332	albuterol pursuant to a standing order.
333	(1) Notwithstanding any other provision of this chapter, a pharmacist or pharmacy
334	intern may dispense an epinephrine auto-injector:
335	(a) (i) to a qualified adult for use in accordance with Title 26, Chapter 41, Emergency

336	Response for Life-threatening Conditions; or
337	(ii) to a qualified epinephrine auto-injector entity for use in accordance with Title 26,
338	Chapter 41, Emergency Response for Life-threatening Conditions;
339	(b) pursuant to a standing prescription drug order made in accordance with Section
340	<u>58-17b-1005;</u>
341	(c) without any other prescription drug order from a person licensed to prescribe an
342	epinephrine auto-injector; and
343	(d) in accordance with the dispensing guidelines in Section 58-17b-1006.
344	(2) Notwithstanding any other provision of this chapter, a pharmacist or pharmacist
345	intern may dispense stock albuterol:
346	(a) (i) to a qualified adult for use in accordance with Title 26, Chapter 41, Emergency
347	Response for Life-threatening Conditions; or
348	(ii) to a qualified stock albuterol entity for use in accordance with Title 26, Chapter 41,
349	Emergency Response for Life-threatening Conditions;
350	(b) pursuant to a standing prescription drug order made in accordance with Section
351	<u>58-17b-1005;</u>
352	(c) without any other prescription drug order from a person licensed to prescribe stock
353	albuterol; and
354	(d) in accordance with the dispensing guidelines in Section 58-17b-1006.
355	Section 11. Section 58-17b-1005 is enacted to read:
356	58-17b-1005. Standing prescription drug orders for epinephrine auto-injectors
357	and stock albuterol.
358	(1) A physician acting in the physician's capacity as an employee of the Department of
359	Health or as a medical director of a local health department may issue a standing prescription
360	drug order authorizing the dispensing of \$→ [the] an ←\$ epinephrine auto-injector under Section
361	58-17b-1004 in accordance with a protocol that:
362	(a) requires the physician to specify the persons, by professional license number,
363	authorized to dispense the epinephrine auto-injector;
364	(b) requires the physician to review at least annually the dispensing practices of those
365	authorized by the physician to dispense the epinephrine auto-injector;
366	(c) requires those authorized by the physician to dispense the epinephrine auto-injector

367	to make and retain a record of each dispensing, including:
368	(i) the name of the qualified adult \$→ [5] or ←\$ qualified epinephrine auto-injector entity
368a	Ŝ→ [, or
369	individual 18 years old or older] ←Ŝ to whom the epinephrine auto-injector is dispensed;
370	(ii) a description of the epinephrine auto-injector dispensed; and
371	(iii) other relevant information; and
372	(d) is approved by the division by administrative rule made in accordance with Title
373	63G, Chapter 3, Utah Administrative Rulemaking Act, in collaboration with the Physicians
374	Licensing Board created in Section 58-67-201 and the Board of Pharmacy.
375	(2) A physician acting in the physician's capacity as an employee of the Department of
376	Health or as a medical director of a local health department may issue a standing prescription
377	drug order authorizing the dispensing of the stock albuterol under Section 58-17b-1004 in
378	accordance with a protocol that:
379	(a) requires the physician to specify the persons, by professional license number,
380	authorized to dispense the stock albuterol;
381	(b) requires the physician to review at least annually the dispensing practices of those
382	authorized by the physician to dispense the stock albuterol;
383	(c) requires those authorized by the physician to dispense the stock albuterol to make
384	and retain a record of each dispensing, including:
385	(i) the name of the qualified adult $\$ \rightarrow [\cdot]$ or $\leftarrow \$$ qualified stock albertal entity $\$ \rightarrow [\cdot]$ or
385a	individual 18
386	<u>years old or older</u>] ←Ŝ to whom the stock albuterol is dispensed;
387	(ii) a description of the stock albuterol dispensed; and
388	(iii) other relevant information; and
389	(d) is approved by the division by administrative rule made in accordance with Title
390	63G, Chapter 3, Utah Administrative Rulemaking Act, in collaboration with the Physicians
391	Licensing Board created in Section 58-67-201 and the board.
392	Section 12. Section 58-17b-1006 is enacted to read:
393	58-17b-1006. Guidelines for dispensing an epinephrine auto-injector and stock
394	albuterol.
395	(1) A pharmacist or pharmacy intern who dispenses an epinephrine auto-injector under
396	this part shall, at a minimum, provide patient counseling to the qualified adult $\hat{S} \rightarrow [\bar{z}]$ or $\leftarrow \hat{S}$
396a	qualified
397	epinephrine auto-injector entity \$→ [, or individual 18 years old or older] ←\$ to whom the
397a	<u>epinephrine</u>

398	auto-injector is dispensed regarding:
399	(a) the appropriate administration and storage of the epinephrine auto-injector;
400	(b) potential side effects and risks of the epinephrine auto-injector; and
401	(c) when to seek emergency medical attention.
402	(2) A pharmacist or pharmacy intern who dispenses stock albuterol under this part
403	shall, at a minimum, provide patient counseling to the qualified adult \$→ [3] or ←\$ qualified stock
403a	<u>albuterol</u>
404	entity \$→ [, or individual 18 years old or older] ←\$ to whom the stock albuterol is dispensed
404a	regarding:
405	(a) the appropriate administration and storage of the stock albuterol;
406	(b) potential side effects and risks of the stock albuterol; and
407	(c) when to seek emergency medical attention.
408	Section 13. Section 58-17b-1007 is enacted to read:
409	58-17b-1007. Limited civil liability.
410	(1) A physician who issues a standing prescription drug order in accordance with
411	Subsection 58-17b-1005(1) is not liable for any civil damages for acts or omissions resulting
412	from the dispensing of an epinephrine auto-injector under this part.
413	(2) A physician who issues a standing prescription drug order in accordance with
414	Subsection 58-17b-1005(2) is not liable for any civil damages for acts or omissions resulting
415	from the dispensing of stock albuterol under this part.
416	Section 14. Section 58-37f-201 is amended to read:
417	58-37f-201. Controlled substance database Creation Purpose.
418	(1) There is created within the division a controlled substance database.
419	(2) The division shall administer and direct the functioning of the database in
420	accordance with this chapter.
421	(3) The division may, under state procurement laws, contract with another state agency
422	or a private entity to establish, operate, or maintain the database.
423	(4) The division shall, in collaboration with the board, determine whether to operate
424	the database within the division or contract with another entity to operate the database, based
425	on an analysis of costs and benefits.
426	(5) The purpose of the database is to contain:
427	(a) the data described in Section 58-37f-203 regarding [every prescription for a
428	controlled substance dispensed in the state to any individual other than an inpatient in a