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S.B. 145
1st Sub. (Green)

Senator Evan J. Vickers proposes the following substitute bill:

PHARMACY PRACTICE ACT AMENDMENTS

2020 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Evan J. Vickers

House Sponsor: Suzanne Harrison

LONG TITLE

General Description:

This bill amends provisions relating to the practice of pharmacy.

Highlighted Provisions:

This bill:

- amends definitions;
- authorizes the dispensing of epinephrine auto-injectors and stock albuterol under certain circumstances;
- authorizes the dispensing of a quantity or dosage form different from a prescription in certain instances;
- amends provisions related to the dispensing of a substitute for albuterol;
- amends provisions relating to emergency refills;
- authorizes the dispensing of certain prescription medical devices without a prescription;
- authorizes a physician to issue a standing prescription drug order for an epinephrine auto-injector or stock albuterol in accordance with a protocol that meets certain requirements;
- exempts a physician from liability for civil damages for acts or omissions resulting from the dispensing of an epinephrine auto-injector or stock albuterol under the

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physician's standing prescription drug order;

- exempts controlled substances dispensed for administration or use in a health care facility outpatient setting from reporting to the state's controlled substance database; and
- makes technical and conforming changes.

Money Appropriated in this Bill:

None

Other Special Clauses:

This bill provides a special effective date.

Utah Code Sections Affected:

AMENDS:

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

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

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

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

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

ENACTS:

58-17b-602.1, Utah Code Annotated 1953

58-17b-610.8, Utah Code Annotated 1953

58-17b-1001, Utah Code Annotated 1953

58-17b-1002, Utah Code Annotated 1953

58-17b-1003, Utah Code Annotated 1953

58-17b-1004, Utah Code Annotated 1953

58-17b-1005, Utah Code Annotated 1953

58-17b-1006, Utah Code Annotated 1953

58-17b-1007, Utah Code Annotated 1953

REPEALS AND REENACTS:

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

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

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

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

As used in this chapter:

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

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

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

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

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

(b) signed by the student's:

(i) parent or guardian; and

(ii) health care provider.

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

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

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

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

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

(c) an advanced practice registered nurse under Section 58-31b-302; or

(d) a physician assistant under Title 58, Chapter 70a, Utah Physician Assistant Act.

(6) "Pharmacist" means the same as that term is defined in Section 58-17b-102.

(7) "Pharmacy intern" means the same as that term is defined in Section 58-17b-102.

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

[~~(6)~~] (9) "Qualified adult" means a person who:

(a) is 18 years of age or older; and

(b) (i) for purposes of administering an epinephrine auto-injector, has successfully completed the training program established in Section 26-41-104; and

(ii) for purposes of administering stock albuterol, has successfully completed the training program established in Section 26-41-104.1.

[~~(7)~~] (10) "Qualified epinephrine auto-injector entity":

(a) means a facility or organization that employs, contracts with, or has a similar relationship with a qualified adult who is likely to have contact with another person who may experience anaphylaxis; and

(b) includes:

(i) recreation camps;

(ii) an education facility, school, or university;

(iii) a day care facility;

(iv) youth sports leagues;

(v) amusement parks;

(vi) food establishments;

(vii) places of employment; and

(viii) recreation areas.

[~~(8)~~] (11) "Qualified stock albuterol entity" means a public or private school that employs, contracts with, or has a similar relationship with a qualified adult who is likely to have contact with another person who may experience an asthma emergency.

[~~(9)~~] (12) "Stock albuterol" means a prescription inhaled medication:

(a) used to treat asthma; and

(b) that may be delivered through a device, including:

(i) an inhaler; or

(ii) a nebulizer with a mouthpiece or mask.

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

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

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

(a) epinephrine auto-injectors for use in accordance with this chapter; or

(b) stock albuterol for use in accordance with this chapter.

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

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

(i) a pharmacist as provided under Section 58-17b-1004; or

(ii) a pharmacy intern as provided under Section 58-17b-1004.

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

(i) a pharmacist as provided under Section 58-17b-1004; or

(ii) a pharmacy intern as provided under Section 58-17b-1004.

(3) A qualified adult:

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

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

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

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

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

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

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

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

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

58-17b-1004 for:

(i) storing:

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

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

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

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

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

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

(c) A qualified stock albuterol entity shall:

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

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

Section 3. Section **58-17b-602.1** is enacted to read:

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

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

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

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

(2) This section does not apply if:

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

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

(c) the prescriber has written or clearly designated "dispense as written" on the

prescription.

Section 4. Section **58-17b-605** is amended to read:

58-17b-605. Drug product equivalents.

(1) For the purposes of this section:

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

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

(b) "Drug product equivalent" means:

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

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

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

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

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

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

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

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

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

(3) (a) Each out-of-state mail service pharmacy dispensing a drug product equivalent as a substitute for another drug into this state shall notify the patient of the substitution either by

telephone or in writing.

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

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

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

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

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

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

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

(i) a generic drug for another generic drug;

(ii) a generic drug for a nongeneric drug;

(iii) a nongeneric drug for another nongeneric drug; or

(iv) a nongeneric drug for a generic drug.

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

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

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

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

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

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

Section 5. Section **58-17b-608** is repealed and reenacted to read:

58-17b-608. Emergency refills.

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

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

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

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

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

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

(f) in the professional judgment of the pharmacist or pharmacy intern the prescription

should be refilled;

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

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

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

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

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

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

(i) a 30-day supply; or

(ii) the quantity last dispensed at the pharmacy pursuant to the prescription as either a fill or a refill; and

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

Section 6. Section **58-17b-610.8** is enacted to read:

58-17b-610.8. Prescription devices.

(1) A pharmacist or pharmacy intern may prescribe and dispense a prescription device described in Subsection (2) to a patient if:

(a) the patient has a current diagnosis, prescription, or treatment protocol from a prescribing practitioner for which one or more of the devices described in Subsection (2) is indicated; and

(b) the pharmacist or pharmacy intern acts in accordance with rules made by the division under Subsection (3).

(2) This section applies to:

(a) nebulizers;

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

(c) diabetic testing supplies.

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

Administrative Rulemaking Act, and in consultation with the board, the Physicians Licensing Board created in Section 58-67-201, and the Osteopathic Physician and Surgeon's Licensing Board created in Section 58-68-201, to implement this section.

Section 7. Section **58-17b-1001** is enacted to read:

Part 10. Epinephrine Auto-Injector and Stock Albuterol Act

58-17b-1001. Title.

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

Section 8. Section **58-17b-1002** is enacted to read:

58-17b-1002. Definitions.

As used in this part:

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

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

(3) "Physician" means the same as that term is defined in Section 58-10-102.

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

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

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

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

Section 9. Section **58-17b-1003** is enacted to read:

58-17b-1003. Voluntary participation.

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

Section 10. Section **58-17b-1004** is enacted to read:

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

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

(a) (i) to a qualified adult for use in accordance with Title 26, Chapter 41, Emergency

Response for Life-threatening Conditions; or

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

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

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

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

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

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

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

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

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

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

Section 11. Section **58-17b-1005** is enacted to read:

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

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

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

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

(c) requires those authorized by the physician to dispense the epinephrine auto-injector

to make and retain a record of each dispensing, including:

(i) the name of the qualified adult, qualified epinephrine auto-injector entity, or individual 18 years old or older to whom the epinephrine auto-injector is dispensed;

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

(iii) other relevant information; and

(d) is approved by the division by administrative rule made in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, in collaboration with the Physicians Licensing Board created in Section 58-67-201 and the Board of Pharmacy.

(2) A physician acting in the physician's capacity as an employee of the Department of Health or as a medical director of a local health department may issue a standing prescription drug order authorizing the dispensing of the stock albuterol under Section 58-17b-1004 in accordance with a protocol that:

(a) requires the physician to specify the persons, by professional license number, authorized to dispense the stock albuterol;

(b) requires the physician to review at least annually the dispensing practices of those authorized by the physician to dispense the stock albuterol;

(c) requires those authorized by the physician to dispense the stock albuterol to make and retain a record of each dispensing, including:

(i) the name of the qualified adult, qualified stock albuterol entity, or individual 18 years old or older to whom the stock albuterol is dispensed;

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

(iii) other relevant information; and

(d) is approved by the division by administrative rule made in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, in collaboration with the Physicians Licensing Board created in Section 58-67-201 and the board.

Section 12. Section **58-17b-1006** is enacted to read:

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

(1) A pharmacist or pharmacy intern who dispenses an epinephrine auto-injector under this part shall, at a minimum, provide patient counseling to the qualified adult, qualified epinephrine auto-injector entity, or individual 18 years old or older to whom the epinephrine

auto-injector is dispensed regarding:

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

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

(c) when to seek emergency medical attention.

(2) A pharmacist or pharmacy intern who dispenses stock albuterol under this part shall, at a minimum, provide patient counseling to the qualified adult, qualified stock albuterol entity, or individual 18 years old or older to whom the stock albuterol is dispensed regarding:

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

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

(c) when to seek emergency medical attention.

Section 13. Section **58-17b-1007** is enacted to read:

58-17b-1007. Limited civil liability.

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

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

Section 14. Section **58-37f-201** is amended to read:

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

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

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

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

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

(5) The purpose of the database is to contain:

(a) the data described in Section 58-37f-203 regarding [~~every prescription for a controlled substance dispensed in the state to any individual other than an inpatient in a~~

~~licensed health care facility~~] prescriptions for dispensed controlled substances;

(b) data reported to the division under Section 26-21-26 regarding poisoning or overdose;

(c) data reported to the division under Subsection 41-6a-502(4) or 41-6a-502.5(5)(b) regarding convictions for driving under the influence of a prescribed controlled substance or impaired driving; and

(d) data reported to the division under Subsection 58-37-8(1)(e) or 58-37-8(2)(j) regarding certain violations of the Utah Controlled Substances Act.

(6) The division shall maintain the database in an electronic file or by other means established by the division to facilitate use of the database for identification of:

(a) prescribing practices and patterns of prescribing and dispensing controlled substances;

(b) practitioners prescribing controlled substances in an unprofessional or unlawful manner;

(c) individuals receiving prescriptions for controlled substances from licensed practitioners, and who subsequently obtain dispensed controlled substances from a drug outlet in quantities or with a frequency inconsistent with generally recognized standards of dosage for that controlled substance;

(d) individuals presenting forged or otherwise false or altered prescriptions for controlled substances to a pharmacy;

(e) individuals admitted to a general acute hospital for poisoning or overdose involving a prescribed controlled substance; and

(f) individuals convicted for:

(i) driving under the influence of a prescribed controlled substance that renders the individual incapable of safely operating a vehicle;

(ii) driving while impaired, in whole or in part, by a prescribed controlled substance; or

(iii) certain violations of the Utah Controlled Substances Act.

Section 15. Section **58-37f-203** is amended to read:

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

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

submit information:

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

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

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

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

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

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

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

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

(i) the requirements of this section;

(ii) the procedures established by the division;

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

(iv) the format established by the division.

(b) A dispensing medical practitioner licensed under Chapter 17b, Part 8, Dispensing Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy, shall comply with the provisions of this section and the dispensing medical practitioner shall assume the duties of the pharmacist under this chapter.

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

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

(ii) each noncontrolled substance that is:

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

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

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

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

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

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

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

(6) The division shall make rules, in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, to establish submission requirements under this part, including:

(a) electronic format;

(b) submission procedures; and

(c) required information and data fields.

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

(a) the identification of each individual who requests or receives information from the database;

(b) the information provided to each individual; and

(c) the date and time that the information is requested or provided.

(8) (a) The division, in collaboration with the Utah Controlled Substance Advisory

Committee created in Section 58-38a-201, shall designate a list of noncontrolled substances described in Subsection (8)(b) by rule made in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act.

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

Section 16. **Effective date.**

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

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

(a) Section 26-41-102;

(b) Section 26-41-105;

(c) Section 58-17b-1001;

(d) Section 58-17b-1002;

(e) Section 58-17b-1003;

(f) Section 58-17b-1004;

(g) Section 58-17b-1005;

(h) Section 58-17b-1006; and

(i) Section 58-17b-1007.