

HB0301S02 compared with HB0301S01

~~text~~ shows text that was in HB0301S01 but was deleted in HB0301S02.

text shows text that was not in HB0301S01 but was inserted into HB0301S02.

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Representative **Raymond P. Ward** proposes the following substitute bill:

MEDICATION DISPENSER AMENDMENTS

2022 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Raymond P. Ward

Senate Sponsor: _____

LONG TITLE

General Description:

This bill enacts provisions relating to the dispensing of drugs by a licensed prescriber.

Highlighted Provisions:

This bill:

- ▶ enacts requirements for licensure as a licensed dispensing practice;
- ▶ permits a prescriber who practices at a licensed dispensing practice to dispense certain drugs to the prescriber's patients ~~if the drug is:~~

~~• not a controlled substance;~~

~~• pre-packaged by the drug's manufacturer, a wholesaler or distributor, or a pharmacy; and~~

~~• is dispensed to the prescriber's patient at the dispensing practice;~~

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- ▶ authorizes the division to perform administrative inspections of a licensed dispensing practice;
- ▶ requires the division to make certain rules regarding the operating standards of a ~~{dispensing}~~licensed practice; and
- ▶ makes technical and conforming changes.

Money Appropriated in this Bill:

None

Other Special Clauses:

None

Utah Code Sections Affected:

AMENDS:

58-17b-302, as last amended by Laws of Utah 2019, First Special Session, Chapter 5

58-17b-309, as last amended by Laws of Utah 2016, Chapter 207

ENACTS:

58-88-201, Utah Code Annotated 1953

58-88-202, Utah Code Annotated 1953

58-88-203, Utah Code Annotated 1953

58-88-204, Utah Code Annotated 1953

58-88-205, Utah Code Annotated 1953

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

Section 1. Section **58-17b-302** is amended to read:

58-17b-302. License required -- License classifications for pharmacy facilities.

(1) A license is required to act as a pharmacy, except:

(a) as specifically exempted from licensure under Section 58-1-307; [~~and~~]

(b) for the operation of a medical cannabis pharmacy under Title 26, Chapter 61a, Utah

Medical Cannabis Act[~~;~~]; and

(c) to operate a licensed dispensing practice under Chapter 88, Part 2, Dispensing

Practice.

(2) The division shall issue a pharmacy license to a facility that qualifies under this chapter in the classification of a:

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- (a) class A pharmacy;
- (b) class B pharmacy;
- (c) class C pharmacy;
- (d) class D pharmacy;
- (e) class E pharmacy; or
- (f) dispensing medical practitioner clinic pharmacy.

(3) (a) Each place of business shall require a separate license.

(b) If multiple pharmacies exist at the same address, a separate license shall be required for each pharmacy.

(4) (a) The division may further define or supplement the classifications of pharmacies.

(b) The division may impose restrictions upon classifications to protect the public health, safety, and welfare.

(5) Each pharmacy shall have a pharmacist-in-charge, except as otherwise provided by rule.

(6) Whenever an applicable statute or rule requires or prohibits action by a pharmacy, the pharmacist-in-charge and the owner of the pharmacy shall be responsible for all activities of the pharmacy, regardless of the form of the business organization.

Section 2. Section **58-17b-309** is amended to read:

58-17b-309. Exemptions from licensure.

In addition to the exemptions from licensure in Section 58-1-307, the following individuals may engage in the acts or practices described in this section without being licensed under this chapter:

(1) a person selling or providing contact lenses in accordance with Section 58-16a-801;

(2) an animal shelter that:

(a) under the indirect supervision of a veterinarian, stores, handles, or administers a drug used for euthanising an animal; and

(b) under the indirect supervision of a veterinarian who is under contract with the animal shelter, stores, handles, or administers a rabies vaccine; ~~and~~

(3) an overdose outreach provider, as defined in Section 26-55-102, that obtains, stores, or furnishes an opiate antagonist in accordance with Title 26, Chapter 55, Opiate Overdose Response Act[-]; and

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(4) a dispensing practitioner, as defined in Section 58-88-201, dispensing a drug under Chapter 88, Part 2, Dispensing Practice.

Section 3. Section **58-88-201** is enacted to read:

CHAPTER 88. GENERAL HEALTH PROFESSIONS

Part 2. Dispensing Practice

58-88-201. Definitions.

As used in this part:

(1) (a) "Dispense" means the delivery by a prescriber of a prescription drug or device to a patient, including the packaging, labeling, and security necessary to prepare and safeguard the drug or device for supplying to a patient.

(b) "Dispense" does not include:

(i) prescribing or administering a drug or device; or

(ii) delivering to a patient a sample packaged for individual use by a licensed manufacturer or re-packager of a drug or device.

(2) "Dispensing practitioner" means an individual who:

(a) is currently licensed as:

(i) a physician and surgeon under Chapter 67, Utah Medical Practice Act;

(ii) an osteopathic physician and surgeon under Chapter 68, Utah Osteopathic Medical Practice Act;

(iii) an advanced practice registered nurse under Subsection 58-31b-301(2)(d); or

(iv) a physician assistant under Chapter 70a, Utah Physician Assistant Act;

(b) is authorized by state law to prescribe and administer drugs in the course of professional practice; and

(c) practices at a licensed dispensing practice.

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

(4) "Health care practice" means:

(a) a health care facility as defined in Section 26-21-2; or

(b) the offices of one or more private prescribers, whether for individual or group practice.

(5) "Licensed dispensing practice" means a health care practice that is licensed as a dispensing practice under Section 58-88-202.

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Section 4. Section **58-88-202** is enacted to read:

58-88-202. Dispensing practice -- Drugs that may be dispensed -- Limitations and exceptions.

(1) Notwithstanding Section 58-17b-302, a dispensing practitioner may dispense a drug at a licensed dispensing practice if the drug is:

~~{~~ (a) not a controlled substance;

~~}~~ (~~b~~)a) packaged in a fixed quantity per package by:

(i) the drug manufacturer;

(ii) a pharmaceutical wholesaler or distributor; or

(iii) a pharmacy licensed under Chapter 17b, Pharmacy Practice Act;~~{ and }~~

(~~c~~)b) dispensed:

(i) at a licensed dispensing practice at which the dispensing practitioner regularly practices; and

(ii) under a prescription issued by the dispensing practitioner to the dispensing practitioner's patient~~{~~

~~{~~ ;

(c) for a condition that is not expected to last longer than 30 days; and

(d) for a condition for which the patient has been evaluated by the dispensing practitioner on the same day on which the dispensing practitioner dispenses the drug.

(2) A dispensing practitioner may not dispense:

(a) a controlled substance as defined in Section 58-37-2;

(b) a drug or class of drugs that is designated by the division under Subsection 58-88-205(2);

(c) gabapentin; or

(d) a supply of a drug under this part that exceeds a 30-day supply.

(3) A dispensing practitioner may not make a claim against workers' compensation or automobile insurance for a drug dispensed under this part for outpatient use unless the dispensing practitioner is contracted with a pharmacy network established by the claim payor.

(4) When a dispensing practitioner dispenses a drug to the patient under this part, a dispensing practitioner shall:

(a) disclose to the patient verbally and in writing that the patient is not required to fill

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the prescription through the licensed dispensing practice and that the patient has a right to fill the prescription through a pharmacy; and

(b) if the patient will be responsible to pay cash for the drug, disclose:

(i) that the patient will be responsible to pay cash for the drug; and

(ii) the amount that the patient will be charged by the licensed dispensing practice for the drug.

(4)5) This part does not:

(a) require a dispensing practitioner to dispense a drug under this part;

(b) limit a health care prescriber from dispensing under Chapter 17b, Part 8,

Dispensing Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy; or

(c) apply to a physician who dispenses:

(i) a drug sample, as defined in Section 58-17b-102, to a patient in accordance with Section 58-1-501.3 or Section 58-17b-610;

(ii) a prescription drug or device to a patient for a patient's immediate need in an emergency department in accordance with Section 58-17b-610.5; or

(iii) a drug in an emergency situation as defined by the division in rule under Chapter 17b, Pharmacy Practice Act.

Section 5. Section **58-88-203** is enacted to read:

58-88-203. Application for licensure as a licensed dispensing practice --

Requirements -- Notification -- Dispensing.

(1) An applicant for licensure as a dispensing practice shall:

(a) submit a written application in the form prescribed by the division;

(b) pay a fee as determined by the department under Section 63J-1-504; and

(c) provide any additional information required by the division by rule.

(2) (a) A dispensing practice shall designate ~~fa contact~~ at least one responsible dispensing practitioner who is responsible for all activities of the licensed dispensing practice related to the dispensing of drugs under this part.

(b) A responsible dispensing practitioner for the licensed dispensing practice shall:

(i) be currently licensed, registered, or otherwise authorized by state law to prescribe and administer drugs in the course of professional practice;

(ii) practice at the licensed dispensing practice;

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(iii) accept responsibility for the operation of the licensed dispensing practice related to the dispensing of drugs under this part and in accordance with all laws and rules relating to the dispensing of drugs at the licensed dispensing practice; and

(iv) be personally in full and actual charge of the operation of the licensed dispensing practice related to the dispensing of drugs under this part.

(c) Whenever an applicable statute or rule requires or prohibits action by a licensed dispensing practice, the responsible dispensing practitioner or practitioners and the owner of the licensed dispensing practice shall be responsible for all activities of the licensed dispensing practice, regardless of the form of the business or entity.

(3) (a) Each license issued under this section shall be issued for a single, specific address, and is not transferable or assignable.

(b) Each license issued under this section shall be issued in accordance with a two-year renewal cycle established by the division by rule.

(c) The division may extend or shorten a renewal period for a period of up to one year to maintain established renewal cycles or to change an established renewal cycle.

(d) Each license automatically expires on the expiration date shown on the license unless the license is renewed by the licensee in accordance with Section 58-1-308.

(4) (a) A **licensed** dispensing practice shall report in writing to the division not later than 10 business days before the date of:

(i) a permanent closure of the **licensed** dispensing practice;

(ii) a change of name or ownership of the **licensed** dispensing practice;

(iii) a change of location of the **licensed** dispensing practice; and

(iv) any matter or occurrence that the division requires by rule to be reported.

(b) As defined by the division by rule, a **licensed** dispensing practice shall report in writing to the division a disaster, accident, or emergency that may affect the purity or labeling of a drug, medication, device, or other material used in the diagnosis or treatment of injury, illness, or disease immediately upon the occurrence of the disaster, accident, or emergency.

(c) A reporting **licensed** dispensing practice shall maintain a copy of any notification required by this Subsection (4) for two years and make a copy of the notification available to the division for inspection at the division's request.

Section 6. Section **58-88-204** is enacted to read:

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58-88-204. Administrative inspections of a dispensing practice -- Penalties.

(1) The division shall conduct audits and inspections of licensed dispensing practices in accordance with standards established by the division by rule.

(2) Penalties for a violation of this part, including fines and citations, shall be issued by the division under:

- (a) Section 58-1-502; and
- (b) the dispensing practitioner's respective licensing chapter.

Section 7. Section **58-88-205** is enacted to read:

58-88-205. Operating standards -- Rulemaking.

(1) The division shall make rules in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, regarding the operating standards for a licensed dispensing practice licensed under this part which shall include, but is not limited to, standards for:

- (a) security;
- (b) labeling;
- (c) storage; and
- (d) supervision.

(2) The division may designate individual medications and classes of medications that may not be dispensed at a licensed dispensing practice under this chapter.

~~(2)~~(3) When making rules under this part, the division shall consult with a group consisting of:

- (a) two members of the Physicians Licensing Board created in Section 58-67-201; and
- (b) two members of the Utah State Board of Pharmacy created in Section 58-17b-201.