HB0301S01 compared with HB0301

~~{deleted text}~~ shows text that was in HB0301 but was deleted in HB0301S01.

inserted text shows text that was not in HB0301 but was inserted into HB0301S01.

DISCLAIMER: This document is provided to assist you in your comparison of the two bills. Sometimes this automated comparison will NOT be completely accurate. Therefore, you need to read the actual bills. This automatically generated document could contain inaccuracies caused by: limitations of the compare program; bad input data; or other causes.

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 ~~{amends}~~enacts provisions relating to ~~{dispensing medical practitioners and dispensing medical practitioner clinic pharmacies}~~the dispensing of drugs by a licensed prescriber.

Highlighted Provisions:

This bill:

- ~~{amends}~~enacts requirements for ~~{a dispensing medical practitioner and dispensing medical practitioner clinic pharmacy}~~licensure as a 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;

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

Money Appropriated in this Bill:

None

Other Special Clauses:

None

Utah Code Sections Affected:

AMENDS:

~~{ **58-17b-102**, as last amended by Laws of Utah 2021, Chapters 127 and 340~~

~~}~~ ~~**{58-17b-802}**~~**58-17b-302**, as last amended by Laws of Utah ~~{2016}~~2019, First Special Session, Chapter ~~{159}~~5

~~**{58-17b-803}**~~**58-17b-309**, as last amended by Laws of Utah ~~{2015, Chapter 206~~

~~**58-17b-804**, as enacted by Laws of Utah 2014, Chapter 72~~

~~**58-17b-805**, as last amended by Laws of Utah 2019, Chapter 343~~

~~**58-17b-806**, as enacted by Laws of Utah 2014, Chapter 72}~~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-102}**~~**58-17b-302** is amended to read:

~~{ **58-17b-102. Definitions.**~~

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

~~(1) "Administering" means:~~

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

~~(b) the placement by a veterinarian with the owner or caretaker of an animal or group of animals of a prescription drug for the purpose of injection, inhalation, ingestion, or any other means directed to the body of the animal by the owner or caretaker in accordance with written or verbal directions of the veterinarian.~~

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

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

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

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

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

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

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

~~(8) "Branch pharmacy" means a pharmacy or other facility in a rural or medically underserved area, used for the storage and dispensing of prescription drugs, which is dependent~~

~~upon, stocked by, and supervised by a pharmacist in another licensed pharmacy designated and approved by the division as the parent pharmacy.~~

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

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

~~(11) "Class B pharmacy":~~

~~(a) means a pharmacy located in Utah:~~

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

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

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

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

~~(12) "Class C pharmacy" means a pharmacy that engages in the manufacture, production, wholesale, or distribution of drugs or devices in Utah.~~

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

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

~~(15) (a) "Closed-door pharmacy" means a pharmacy that:~~

~~(i) provides pharmaceutical care to a defined and exclusive group of patients who have access to the services of the pharmacy because they are treated by or have an affiliation with a specific entity, including a health maintenance organization or an infusion company; or~~

~~(ii) engages exclusively in the practice of telepharmacy and does not serve walk-in retail customers.~~

~~(b) "Closed-door pharmacy" does not include a hospital pharmacy, a retailer of goods to the general public, or the office of a practitioner.~~

~~(16) "Collaborative pharmacy practice" means a practice of pharmacy whereby one or more pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or~~

~~more practitioners under protocol whereby the pharmacist may perform certain pharmaceutical care functions authorized by the practitioner or practitioners under certain specified conditions or limitations.~~

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

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

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

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

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

~~(b) "Compounding" does not include:~~

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

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

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

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

~~(20) "Controlled substance" means the same as that term is defined in Section 58-37-2.~~

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

~~(22) "Dispense" means the interpretation, evaluation, and implementation of a prescription drug order or device or nonprescription drug or device under a lawful order of a~~

~~practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient, research subject, or an animal.~~

~~(23) "Dispensing medical practitioner" means an individual who is[: (a) 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) a physician assistant under Chapter 70a, Utah Physician Assistant Act; (iv) a nurse practitioner under Chapter 31b, Nurse Practice Act; or (v) an optometrist under Chapter 16a, Utah Optometry Practice Act, if the optometrist is acting within the scope of practice for an optometrist; and (b) licensed by the division under the Pharmacy Practice Act] authorized to engage in [the practice of] practice as a dispensing medical practitioner under Section 58-17b-80.~~

~~(24) "Dispensing medical practitioner clinic pharmacy" means a closed-door pharmacy located within a licensed dispensing medical practitioner's place of practice.~~

~~(25) "Distribute" means to deliver a drug or device other than by administering or dispensing.~~

~~(26) (a) "Drug" means:~~

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

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

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

~~(iv) substances intended for use as a component of any substance specified in Subsections (26)(a)(i), (ii), (iii), and (iv).~~

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

~~(27) "Drug regimen review" includes the following activities:~~

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

~~(i) known allergies;~~

~~(ii) rational therapy-contraindications;~~

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

~~(iv) reasonable directions for use;~~

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

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

~~(i) drug-drug;~~

~~(ii) drug-food;~~

~~(iii) drug-disease; and~~

~~(iv) adverse drug reactions; and~~

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

~~(28) "Drug sample" means a prescription drug packaged in small quantities consistent with limited dosage therapy of the particular drug, which is marked "sample", is not intended to be sold, and is intended to be provided to practitioners for the immediate needs of patients for trial purposes or to provide the drug to the patient until a prescription can be filled by the patient.~~

~~(29) "Electronic signature" means a trusted, verifiable, and secure electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record.~~

~~(30) "Electronic transmission" means transmission of information in electronic form or the transmission of the exact visual image of a document by way of electronic equipment.~~

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

~~(32) "Legend drug" has the same meaning as prescription drug.~~

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

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

~~(35) (a) "Manufacturing" means:~~

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

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

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

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

~~(36) "Medical order" means a lawful order of a practitioner which may include a prescription drug order.~~

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

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

~~(39) (a) "Nonprescription drug" means a drug which:~~

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

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

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

~~(40) "Nonresident pharmacy" means a pharmacy located outside of Utah that sells to a person in Utah.~~

~~(41) "Nuclear pharmacy" means a pharmacy providing radio-pharmaceutical service.~~

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

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

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

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

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

(44) "Pharmaceutical administration facility" means a facility, agency, or institution in which:

(a) prescription drugs or devices are held, stored, or are otherwise under the control of the facility or agency for administration to patients of that facility or agency;

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

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

(45) (a) "Pharmaceutical care" means carrying out the following in collaboration with a prescribing practitioner, and in accordance with division rule:

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

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

(iii) arresting or slowing a disease process.

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

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

(47) (a) "Pharmaceutical wholesaler or distributor" means a pharmaceutical facility

~~engaged in the business of wholesale vending or selling of a prescription drug or device to other than a consumer or user of the prescription drug or device that the pharmaceutical facility has not produced, manufactured, compounded, or dispensed.~~

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

~~(i) intracompany sales;~~

~~(ii) the sale, purchase, or trade of a prescription drug or device, or an offer to sell, purchase, or trade a prescription drug or device, if the activity is carried out between one or more of the following entities under common ownership or common administrative control, as defined by division rule:~~

~~(A) hospitals;~~

~~(B) pharmacies;~~

~~(C) chain pharmacy warehouses, as defined by division rule; or~~

~~(D) other health care entities, as defined by division rule;~~

~~(iii) the sale, purchase, or trade of a prescription drug or device, or an offer to sell, purchase, or trade a prescription drug or device, for emergency medical reasons, including supplying another pharmaceutical facility with a limited quantity of a drug, if:~~

~~(A) the facility is unable to obtain the drug through a normal distribution channel in sufficient time to eliminate the risk of harm to a patient that would result from a delay in obtaining the drug; and~~

~~(B) the quantity of the drug does not exceed an amount reasonably required for immediate dispensing to eliminate the risk of harm;~~

~~(iv) the distribution of a prescription drug or device as a sample by representatives of a manufacturer; and~~

~~(v) the distribution of prescription drugs, if:~~

~~(A) the facility's total distribution-related sales of prescription drugs does not exceed 5% of the facility's total prescription drug sales; and~~

~~(B) the distribution otherwise complies with 21 C.F.R. Sec. 1307.11.~~

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

~~(49) "Pharmacist-in-charge" means a pharmacist currently licensed in good standing~~

~~who accepts responsibility for the operation of a pharmacy in conformance with all laws and rules pertinent to the practice of pharmacy and the distribution of drugs, and who is personally in full and actual charge of the pharmacy and all personnel.~~

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

~~(51) "Pharmacy" means any place where:~~

~~(a) drugs are dispensed;~~

~~(b) pharmaceutical care is provided;~~

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

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

~~(52) "Pharmacy benefits manager or coordinator" means a person or entity that provides a pharmacy benefits management service as defined in Section 31A-46-102 on behalf of a self-insured employer, insurance company, health maintenance organization, or other plan sponsor, as defined by rule.~~

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

~~(54) "Pharmacy technician training program" means an approved technician training program providing education for pharmacy technicians.~~

~~(55) (a) "Practice as a dispensing medical practitioner" means the practice of pharmacy, specifically relating to the dispensing of a prescription drug in accordance with Part 8, Dispensing Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy, and division rule adopted after consultation with the Board of pharmacy and the governing boards of the practitioners described in [Subsection (23)(a)]~~ Section 58-17b-802~~.~~

~~(b) "Practice as a dispensing medical practitioner" does not include:~~

~~(i) using a vending type of dispenser as defined by the division by administrative rule; or~~

~~(ii) except as permitted by Section 58-17b-805, dispensing of a controlled substance as defined in Section 58-37-2.~~

~~(56) "Practice as a licensed pharmacy technician" means engaging in practice as a pharmacy technician under the general supervision of a licensed pharmacist and in accordance~~

~~with a scope of practice defined by division rule made in collaboration with the board.~~

~~(57) "Practice of pharmacy" includes the following:~~

~~(a) providing pharmaceutical care;~~

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

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

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

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

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

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

~~(d) participating in drug utilization review;~~

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

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

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

~~(h) providing drug product equivalents;~~

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

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

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

~~(l) telepharmacy;~~

~~(m) formulary management intervention;~~

~~(n) prescribing and dispensing a self-administered hormonal contraceptive in accordance with Title 26, Chapter 64, Family Planning Access Act; and~~

~~(o) issuing a prescription in accordance with Section 58-17b-627.~~

~~(58) "Practice of telepharmacy" means the practice of pharmacy through the use of telecommunications and information technologies.~~

~~(59) "Practice of telepharmacy across state lines" means the practice of pharmacy through the use of telecommunications and information technologies that occurs when the patient is physically located within one jurisdiction and the pharmacist is located in another jurisdiction.~~

~~(60) "Practitioner" means an individual currently licensed, registered, or otherwise authorized by the appropriate jurisdiction to prescribe and administer drugs in the course of professional practice.~~

~~(61) "Prescribe" means to issue a prescription:~~

~~(a) orally or in writing; or~~

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

~~(62) "Prescription" means an order issued:~~

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

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

~~(63) "Prescription device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, and any component part or accessory, which is required under federal or state law to be prescribed by a practitioner and dispensed by or through a person or entity licensed under this chapter or exempt from licensure under this chapter.~~

~~(64) "Prescription drug" means a drug that is required by federal or state law or rule to be dispensed only by prescription or is restricted to administration only by practitioners.~~

~~(65) "Repackage":~~

~~(a) means changing the container, wrapper, or labeling to further the distribution of a prescription drug; and~~

~~(b) does not include:~~

~~(i) Subsection (65)(a) when completed by the pharmacist responsible for dispensing the product to a patient; or~~

(ii) changing or altering a label as necessary for a dispensing practitioner under Part 8, Dispensing Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy, for dispensing a product to a patient.

(66) "Research using pharmaceuticals" means research:

(a) conducted in a research facility, as defined by division rule, that is associated with a university or college in the state accredited by the Northwest Commission on Colleges and Universities;

(b) requiring the use of a controlled substance, prescription drug, or prescription device;

(c) that uses the controlled substance, prescription drug, or prescription device in accordance with standard research protocols and techniques, including, if required, those approved by an institutional review committee; and

(d) that includes any documentation required for the conduct of the research and the handling of the controlled substance, prescription drug, or prescription device.

(67) "Retail pharmacy" means a pharmaceutical facility dispensing prescription drugs and devices to the general public.

(68) (a) "Self-administered hormonal contraceptive" means a self-administered hormonal contraceptive that is approved by the United States Food and Drug Administration to prevent pregnancy.

(b) "Self-administered hormonal contraceptive" includes an oral hormonal contraceptive, a hormonal vaginal ring, and a hormonal contraceptive patch.

(c) "Self-administered hormonal contraceptive" does not include any drug intended to induce an abortion, as that term is defined in Section 76-7-301.

(69) "Self-audit" means an internal evaluation of a pharmacy to determine compliance with this chapter.

(70) "Supervising pharmacist" means a pharmacist who is overseeing the operation of the pharmacy during a given day or shift.

(71) "Supportive personnel" means unlicensed individuals who:

(a) may assist a pharmacist, pharmacist preceptor, pharmacy intern, or licensed pharmacy technician in nonjudgmental duties not included in the definition of the practice of pharmacy, practice of a pharmacy intern, or practice of a licensed pharmacy technician, and as

~~those duties may be further defined by division rule adopted in collaboration with the board; and~~

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

~~(72) "Unlawful conduct" means the same as that term is defined in Sections 58-1-501 and 58-17b-501.~~

~~(73) "Unprofessional conduct" means the same as that term is defined in Sections 58-1-501 and 58-17b-502 and may be further defined by rule.~~

~~(74) "Veterinary pharmaceutical facility" means a pharmaceutical facility that dispenses drugs intended for use by animals or for sale to veterinarians for the administration for animals.~~

~~}~~ **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 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:

(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~~{.~~

~~Section 2. Section **58-17b-802** is amended to read:~~

~~**58-17b-802. Definitions**}~~[:]; and

(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) "~~{Cosmetic drug}~~Dispense" means the delivery by a prescriber of a prescription drug ~~{that:~~

~~(i) is for the purpose of promoting attractiveness or altering the appearance of an individual; and~~

~~(ii) (A) is listed as a cosmetic drug subject to the exemption under this section by the division by administrative rule; or~~

~~(B) has been expressly approved for online dispensing, whether or not it is dispensed online or through a physician's office.~~

~~(b) "Cosmetic 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~~{ a prescription drug that is:~~

~~(i) a controlled substance;~~

~~(ii) compounded by the physician; or~~

~~(iii) prescribed for or used by the patient for the purpose of diagnosing, curing, or preventing a disease.~~

~~(2) "Employer sponsored clinic" means:~~

~~(a) an entity that has a medical director who is licensed as a physician as defined in Section 58-67-102 and offers health care, as defined in Section 31A-1-301, only to the employees of an exclusive group of employers and the employees' dependents; or~~

~~(b) a clinic designated as a clinic for state employees and their dependents by the Public Employees' Benefit and Insurance Program under the pilot program created by Section 49-20-413 including all the patients at that clinic, regardless of the patients' participation in the pilot program.~~

~~[(3) "Health care" is as defined in Section 31A-1-301.]~~

~~[(4)] (3) (a) "Injectable weight loss drug" means an injectable prescription drug:~~

~~(i) prescribed to promote weight loss; and~~

~~(ii) listed as an injectable prescription drug subject to exemption under this section by the division by administrative rule.~~

~~(b) "Injectable weight loss drug" does not include a prescription drug that is a controlled substance.~~

~~(4) "Physician}~~:

(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~~{ holds a valid license}~~:

(a) is currently licensed as:

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

(~~{~~b~~}~~ii) an osteopathic physician and surgeon under Chapter 68, Utah Osteopathic Medical Practice Act~~{~~.

~~(5) "Prepackaged drug" means a prescription drug that:~~

~~(a) is not listed under federal or state law as a Schedule I, II, III, IV, or V drug; and~~

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

~~(i) the drug manufacturer;~~

~~(ii) a pharmaceutical wholesaler or distributor; or~~

~~(iii) a pharmacy licensed under this title.~~

~~Section 3. Section **58-17b-803** is amended to read:~~

~~**58-17b-803. Qualifications to practice as a dispensing medical practitioner -- Scope of practice.**~~

~~(1) An individual may practice as a dispensing medical practitioner if the individual holds a valid license as:~~

~~(a) a physician;~~

~~(b)~~~~}~~;

(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;

(~~{~~c) ~~a nurse practitioner under Chapter 31b, Nurse Practice Act; or~~

~~(d) an optometrist under Chapter 16a, Utah Optometry Practice Act, if the optometrist is acting within the scope of practice of an optometrist.~~

~~{(1) An applicant for a license}~~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 ~~{medical practitioner shall:}~~

~~[(a) be licensed in good standing under at least one of the chapters listed in Subsection 58-17b-102(23)(a); and]~~

~~[(b) submit an application for a license as a dispensing medical practitioner in a form prescribed by the division and pay a fee established by the division.]~~

~~(2) The division shall accept the [licensing in good standing under] qualifications described in Subsection (1) in lieu of requiring an applicant for a license under this part to comply with Sections 58-17b-303 and 58-17b-307.~~

~~(3) A dispensing medical practitioner may dispense, at a dispensing medical practitioner clinic pharmacy and in accordance with this part:~~

~~(a) a cosmetic drug and an injectable weight loss drug if:~~

~~(i) the drug was prescribed by the dispensing medical practitioner to the dispensing medical practitioner's patient; and~~

~~(ii) the dispensing medical practitioner complies with administrative rules adopted by the division}~~practice under Section ~~{58-17b-802;~~

~~(b) a cancer drug treatment regimen if the dispensing medical practitioner complies with Section 58-17b-805; and~~

~~(c) a pre-packaged drug to an employee or a dependent of an employee at an employer sponsored clinic if the dispensing medical practitioner:~~

~~(i) treats an employee, or the dependent of an employee, of one of an exclusive group of employers at an employer sponsored clinic;~~

~~(ii) prescribes a prepackaged drug to the employee or the employee's dependent;~~

~~(iii) dispenses the prepackaged drug at the employer sponsored clinic; and~~

~~(iv) complies with administrative rules adopted by the division in consultation with the [Board of Pharmacy] board that establish labeling, record keeping, patient counseling, purchasing and distribution, operating, treatment, quality of care, and storage requirements.~~

~~(4) A dispensing medical practitioner:~~

~~(a) shall inform the patient:~~

~~(i) that the drug dispensed by the practitioner may be obtained from a pharmacy~~

~~unaffiliated with the practitioner;~~

~~(ii) of the directions for appropriate use of the dispensed drug;~~

~~(iii) of potential side effects to the use of the dispensed drug; and~~

~~(iv) how to contact the dispensing medical practitioner if the patient has questions or concerns regarding the drug;~~

~~(b) shall report to the controlled substance database in the same manner as required in Section 58-37f-203; and~~

~~(c) may delegate the dispensing of the drug if the individual to whom the dispensing was delegated is:~~

~~(i) employed by the dispensing medical practitioner or the outpatient clinic setting in which the dispensing medical practitioner works; and~~

~~(ii) acting under the direction of a dispensing medical practitioner who is immediately available on site for any necessary consultation.~~

~~(5) If the chapter that governs the license of a dispensing medical practitioner[, as listed in Subsection 58-17b-102(23),] requires physician supervision in its scope of practice requirements, the dispensing medical practitioner shall only dispense a drug under the supervision of [an individual licensed under Chapter 67, Utah Medical Practice Act, or Chapter 68, Utah Osteopathic Medical Practice Act] a physician.~~

~~(6) A dispensing medical practitioner may not dispense a drug under this part for outpatient use if:~~

~~(a) the claim is for a workers' compensation or automobile insurance claim; and~~

~~(b) the dispensing medical practitioner is not contracted with a pharmacy network established by the claim payor}~~58-88-202.

Section 4. Section ~~{**58-17b-804** is amended to read:~~

~~**58-17b-804. Qualifications for licensure as a dispensing medical practitioner clinic pharmacy.**~~

~~(1) An applicant for a license as a dispensing medical practitioner clinic pharmacy shall comply with Section 58-17b-306.~~

~~(2) (a)}~~**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) packaged in a fixed quantity per package by:

(i) the drug manufacturer;

(ii) a pharmaceutical wholesaler or distributor; or

(iii) a pharmacy licensed under ~~{this part is not required to have a pharmacist-in-charge if:~~

~~(i) the pharmacy has designated a dispensing medical practitioner as responsible for all activities of the pharmacy; and~~

~~(ii) the pharmacy complies with administrative rules adopted};~~ Chapter 17b, Pharmacy Practice Act; and

(c) dispensed:

(i) at a 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.

(2) A dispensing practitioner may not dispense 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) 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 ~~{consultation with~~

~~the Board of Pharmacy and the practitioners' respective governing bodies [of the practitioners described in Subsection 58-17b-102(23)(a)].~~

~~(b) Notwithstanding Subsection 58-17b-306(1)(e), the division, in consultation with the Board of Pharmacy and the practitioners' respective governing boards [of the practitioners described in Subsection 58-17b-102(23)(a)], may modify the operating standards for a dispensing medical practitioner clinic pharmacy.}~~rule under Chapter 17b, Pharmacy Practice Act.

Section 5. Section ~~{**58-17b-805** is amended to read:~~

~~**58-17b-805. Dispensing medical practitioner -- Cancer drug treatment regimen.**~~

~~(1) For purposes of this section:~~

~~(a) "Cancer drug treatment regimen" means a prescription drug used to treat cancer, manage its symptoms, or provide continuity of care for a cancer patient.~~

~~(b) "Cancer drug treatment regimen" includes:~~

~~(i) a chemotherapy drug administered intravenously, orally, rectally, or by dermal methods; and~~

~~(ii) a drug used to support cancer treatment, including a drug used to treat, alleviate, or minimize physical and psychological symptoms or pain, to improve patient tolerance of cancer treatments, or to prepare a patient for a subsequent course of therapy.~~

~~(c) "Cancer drug treatment regimen" does not mean a drug listed under federal law as a Schedule I, II, or III drug.~~

~~(2) [An individual may be licensed}~~**58-88-203** is enacted to read:

58-88-203. Application for licensure as a dispensing ~~{medical practitioner with a scope of practice that permits}~~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 dispensing practice shall designate a contact dispensing practitioner who is responsible for all activities of the dispensing ~~{medical practitioner to] A dispensing medical practitioner may prescribe and dispense a cancer drug treatment regimen if the individual:~~

~~(a) is [licensed as described in Subsections 58-17b-102(23)(a)(i) and (ii)] a physician;~~

~~and~~

~~(b) is certified or eligible to be certified by:~~

~~(i) the American Board of Internal Medicine in medical oncology; or~~

~~(ii) the American Board of Urology.~~

~~(3) A dispensing medical practitioner authorized to prescribe and dispense a cancer drug treatment regimen}~~practice related to the dispensing of drugs under this part.

(3) (a) Each license issued under this section ~~{may prescribe and dispense a cancer drug treatment regimen:~~

~~(a) to the dispensing medical practitioner's patient who is currently undergoing chemotherapy in an outpatient clinic setting; and~~

~~(b) if the dispensing medical practitioner determines that providing the cancer drug treatment regimen to the patient in the outpatient clinic setting is in the best interest of the patient or provides better access to care for the patient.}~~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 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 dispensing practice;

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

(iii) a change of location of the 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 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 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 ~~{**58-17b-806** is amended to read:~~

~~**58-17b-806. Enforcement of dispensing medical practitioner and dispensing medical practitioner clinic pharmacy compliance with Pharmacy Practice Act.**~~

~~(1) (a) The}~~**58-88-204** is enacted to read:

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 dispensing practice licensed under this part.

(2) When making rules under this part, the division shall consult with ~~{the dispensing medical practitioner's appropriate licensing board [as designated in Subsection 58-17b-102(23)(a)] regarding a violation of this chapter[; and].~~

~~(b) [the Pharmacy Board] The board shall, if requested by the licensing board of the dispensing medical practitioner, assist the licensing board for the dispensing medical practitioner with reviewing the violations of the provisions of this chapter.~~

~~(2) The division may take appropriate action against a dispensing medical practitioner, in accordance with this chapter, if the dispensing medical practitioner's appropriate licensing board [designated in Subsection 58-17b-102(23)(a)] recommends to the division that action be taken under this chapter.~~

~~(3) The division, in consultation with the board, is the primary enforcer under this chapter for a dispensing medical practitioner clinic pharmacy licensed under}~~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-804}~~58-17b-201.