

## Chapter 17b Pharmacy Practice Act

### Part 1 General Provisions

#### **58-17b-101 Title.**

This chapter is known as the "Pharmacy Practice Act."

Enacted by Chapter 280, 2004 General Session

#### **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) "Closed-door pharmacy" means a pharmacy that 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, but not including 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, 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 to engage in the practice of a dispensing medical practitioner.
- (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 49-20-502 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).
  - (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)

- (a) "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.
- (b) "Practice as a licensed pharmacy technician" does not include:
  - (i) performing a drug utilization review, prescription drug order clarification from a prescriber, final review of the prescription, dispensing of the drug, or counseling a patient with respect to a prescription drug;
  - (ii) except as permitted by rules made by the division in consultation with the board, final review of a prescribed drug prepared for dispensing;
  - (iii) counseling regarding nonprescription drugs and dietary supplements unless delegated by the supervising pharmacist; or
  - (iv) receiving new prescription drug orders when communicating telephonically or electronically unless the original information is recorded so the pharmacist may review the prescription drug order as transmitted.

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

Amended by Chapter 295, 2018 General Session

**58-17b-103 Administrative inspections.**

- (1) The division may for the purpose of ascertaining compliance with the provisions of this chapter, require a self-audit or enter and inspect the business premises of a person:
  - (a) licensed under Part 3, Licensing; or
  - (b) who is engaged in activities that require a license under Part 3, Licensing.
- (2) Before conducting an inspection under Subsection (1), the division shall, after identifying the person in charge:
  - (a) give proper identification;
  - (b) request to see the applicable license or licenses;
  - (c) describe the nature and purpose of the inspection; and
  - (d) provide upon request, the authority of the division to conduct the inspection and the penalty for refusing to permit the inspection as provided in Section 58-17b-504.
- (3) In conducting an inspection under Subsection (1), the division may, after meeting the requirements of Subsection (2):
  - (a) examine any record, prescription, order, drug, device, equipment, machine, electronic device or media, or area related to activities for which a license has been issued or is required by Part 3, Licensing, for the purpose of ascertaining compliance with the applicable provisions of this chapter;
  - (b) reproduce any record or media at the division's own cost;
  - (c) take a drug or device for further analysis if considered necessary;
  - (d) temporarily seize a drug or device that is suspected to be adulterated, misbranded, outdated, or otherwise in violation of this chapter, pending an adjudicative proceeding on the matter;
  - (e) box and seal drugs suspected to be adulterated, outdated, misbranded, or otherwise in violation of this chapter; and
  - (f) dispose of or return a drug or device obtained under this Subsection (3) in accordance with procedures established by division rule.
- (4) An inspection described in Subsection (1) shall be conducted during regular business hours.

- (5) If, upon inspection, the division concludes that a person has violated the provisions of this chapter or Chapter 37, Utah Controlled Substances Act, or a rule or order issued with respect to those chapters, and that disciplinary action is appropriate, the director or the director's designee shall promptly issue a fine or citation to the licensee in accordance with Section 58-17b-504.

Amended by Chapter 262, 2013 General Session

Amended by Chapter 278, 2013 General Session

## **Part 2 Board**

### **58-17b-201 Board -- Membership -- Qualifications -- Terms.**

- (1) There is created the Utah State Board of Pharmacy consisting of five pharmacists, one pharmacy technician, and one member of the general public.
- (a) The public member of the board shall be a Utah resident who:
- (i) is 21 years of age or older;
  - (ii) has never been licensed to engage in the practice of pharmacy;
  - (iii) has never been the spouse of a person licensed to engage in the practice of pharmacy;
  - (iv) has never held any material financial interest in pharmacy practice; and
  - (v) has never engaged in any activity directly related to the practice of pharmacy.
- (b) The licensed pharmacist and licensed pharmacy technician members of the board shall:
- (i) have been Utah residents continuously for at least three years;
  - (ii) have at least five years experience in the practice of pharmacy in good standing with the division in Utah after licensure; and
  - (iii) maintain licensure in good standing to engage in the practice of pharmacy or practice as a pharmacy technician in Utah for the duration of the appointment.
- (2) The board shall be appointed and serve in accordance with Section 58-1-201.
- (3) The duties and responsibilities of the board are in accordance with Sections 58-1-202 and 58-1-203, and as required under Section 58-37f-202 regarding the controlled substance database. In addition, the board shall designate an appropriate member on a permanent or rotating basis to:
- (a) assist the division in reviewing complaints concerning the unlawful or unprofessional conduct of a licensee; and
  - (b) advise the division in its investigation of these complaints.
- (4) A board member who has, under Subsection (3), reviewed a complaint or advised in its investigation may be disqualified from participating with the board when the board serves as a presiding officer in an adjudicative proceeding concerning the complaint.
- (5) A board member may be removed in accordance with Subsection 58-1-201(2)(e) or upon one of the following grounds:
- (a) refusal or inability for any reason of a board member to perform his duties as a member of the Board in an efficient, responsible, and professional manner;
  - (b) misuse of appointment to obtain personal, pecuniary, or material gain or advantage for himself or another through such appointment; or
  - (c) violation of the laws governing the practice of pharmacy or Chapter 37, Utah Controlled Substances Act.

Amended by Chapter 287, 2010 General Session

### **Part 3 Licensing**

#### **58-17b-301 License required -- License classifications for individuals.**

- (1) A license is required to engage in the practice of pharmacy, telepharmacy, pharmacy technician, or dispensing medical practitioner except as specifically provided in Section 58-1-307 or 58-17b-309.
- (2) The division shall issue to an individual who qualifies under this chapter a license in the classification of:
  - (a) pharmacist;
  - (b) pharmacy intern;
  - (c) pharmacy technician;
  - (d) dispensing medical practitioner; or
  - (e) pharmacy technician trainee.

Amended by Chapter 72, 2014 General Session

Amended by Chapter 385, 2014 General Session

Amended by Chapter 385, 2014 General Session

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

- (1) A license is required to act as a pharmacy, except as specifically exempted from licensure under Section 58-1-307.
- (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) Each place of business shall require a separate license. If multiple pharmacies exist at the same address, a separate license shall be required for each pharmacy.
- (4) The division may further define or supplement the classifications of pharmacies. 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.

Amended by Chapter 72, 2014 General Session

#### **58-17b-303 Qualifications for licensure as a pharmacist.**

- (1) An applicant for licensure as a pharmacist shall:

- (a) submit an application in a form prescribed by the division;
  - (b) pay a fee as determined by the department under Section 63J-1-504;
  - (c) produce satisfactory evidence of good moral character as it relates to the applicant's ability to practice pharmacy;
  - (d) complete a criminal background check and be free from criminal convictions as described in Section 58-1-501;
  - (e) have no physical or mental condition of a nature which prevents the applicant from engaging in the practice of pharmacy with reasonable skill, competency, and safety to the public;
  - (f) have graduated and received a professional entry degree from a school or college of pharmacy which is accredited by the Accreditation Council on Pharmacy Education;
  - (g) have completed an internship meeting standards established by division rule made in collaboration with the board; and
  - (h) have successfully passed examinations required by division rule made in collaboration with the board.
- (2) An applicant for licensure as a pharmacist whose pharmacy education was completed at a foreign pharmacy school shall, in addition to the requirements under Subsections (1)(a) through (e), (g), and (h), obtain a certification of equivalency from a credentialing agency required by division rule made in collaboration with the board.
- (3) An applicant for a license by endorsement as a pharmacist under this section shall:
- (a) submit a written application in the form prescribed by the division;
  - (b) pay the fee determined by the department under Section 63J-1-504;
  - (c) be of good moral character as required of applicants for licensure as pharmacists under Subsection (1);
  - (d) complete a criminal background check and be free from criminal convictions as described in Section 58-1-501;
  - (e) have no physical or mental condition of a nature which prevents the applicant from engaging in the practice of pharmacy with reasonable skill, competency, and safety to the public;
  - (f) have lawfully practiced as a licensed pharmacist a minimum of 2,000 hours in the four years immediately preceding the date of application;
  - (g) produce satisfactory evidence of completing the professional education required under Subsection (1);
  - (h) be currently licensed in good standing as a pharmacist in another state, territory, or possession of the United States;
  - (i) produce satisfactory evidence that the examination requirements are or were at the time the license was issued, equal to those of this state; and
  - (j) pass the jurisprudence examination prescribed by division rule made in collaboration with the board.

Amended by Chapter 93, 2012 General Session

**58-17b-304 Qualifications for licensure of pharmacy intern.**

An applicant for licensure as a pharmacy intern shall:

- (1) submit an application in a form prescribed by the division;
- (2) pay a fee determined by the department under Section 63J-1-504;
- (3) produce satisfactory evidence of good moral character as it relates to the applicant's ability to practice pharmacy;
- (4) complete a criminal background check and be free from criminal convictions as described in Section 58-1-501;

- (5) have no physical or mental condition of a nature which prevents the applicant from engaging in the practice of pharmacy with reasonable skill, competency, and safety to the public;
- (6) meet the preliminary educational qualifications required by division rule made in collaboration with the board; and
- (7) meet one of the following educational criteria:
  - (a) be a current pharmacy student, a resident, or fellow in a program approved by division rule made in collaboration with the board; or
  - (b) have graduated from a foreign pharmacy school and received certification of equivalency from a credentialing agency approved by division rule made in collaboration with the board.

Amended by Chapter 166, 2013 General Session

**58-17b-305 Qualifications for licensure of pharmacy technician.**

- (1) An applicant for licensure as a pharmacy technician shall:
  - (a) submit an application in a form prescribed by the division;
  - (b) pay a fee determined by the department under Section 63J-1-504;
  - (c) produce satisfactory evidence of good moral character as it relates to the applicant's ability to practice pharmacy;
  - (d) complete a criminal background check and be free from criminal convictions as described in Section 58-1-501;
  - (e) have no physical or mental condition of a nature which prevents the applicant from engaging in practice as a pharmacy technician with reasonable skill, competency, and safety to the public;
  - (f) have completed a program and curriculum of education and training, meeting standards established by division rule made in collaboration with the board; and
  - (g) successfully complete the examinations requirement within the time periods established by division rule made in collaboration with the board.
- (2) A pharmacist whose license has been denied, revoked, suspended, or restricted for disciplinary purposes is not eligible to be a licensed pharmacy technician while on probation with the division.

Amended by Chapter 166, 2013 General Session

**58-17b-305.1 Qualifications for licensure of pharmacy technician trainee.**

- (1) An applicant for licensure as a pharmacy technician trainee shall:
  - (a) submit an application to the division on a form created by the division;
  - (b) pay a fee established by the division in accordance with Section 63J-1-504;
  - (c) submit satisfactory evidence, as determined by the division, of good moral character as it relates to the applicant's ability to practice pharmacy;
  - (d) unless exempted by the division, submit a completed criminal background check;
  - (e) demonstrate, as determined by the division, that the applicant does not have a physical or mental condition that would prevent the applicant from engaging in practice as a pharmacy technician with reasonable skill, competency, and safety to the public; and
  - (f) submit evidence that the applicant is enrolled in a training program approved by the division.
- (2) A pharmacist whose license has been denied, revoked, suspended, or restricted for disciplinary purposes is not eligible to be licensed as a pharmacy technician trainee during division probation.

Enacted by Chapter 385, 2014 General Session

**58-17b-306 Qualifications for licensure as a pharmacy.**

- (1) Each applicant for licensure under this section, except for those applying for a class D license, 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;
  - (c) satisfy the division that the applicant, and each owner, officer, or manager of the applicant have not engaged in any act, practice, or omission, which when considered with the duties and responsibilities of a licensee under this section indicates there is cause to believe that issuing a license to the applicant is inconsistent with the interest of the public's health, safety, or welfare;
  - (d) demonstrate the licensee's operations will be in accordance with all federal, state, and local laws relating to the type of activity engaged in by the licensee, including regulations of the Federal Drug Enforcement Administration and Food and Drug Administration;
  - (e) maintain operating standards established by division rule made in collaboration with the board; and
  - (f) acknowledge the division's authority to inspect the licensee's business premises pursuant to Section 58-17b-103.
- (2) Each applicant applying for a class D license 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;
  - (c) present to the division verification of licensure in the state where physically located and verification that such license is in good standing;
  - (d) provide a statement of the scope of pharmacy services that will be provided and a detailed description of the protocol as described by rule by which pharmacy care will be provided, including any collaborative practice arrangements with other health care practitioners;
  - (e) sign an affidavit attesting that any healthcare practitioners employed by the applicant and physically located in Utah have the appropriate license issued by the division and in good standing;
  - (f) sign an affidavit attesting that the applicant will abide by the pharmacy laws and regulations of the jurisdiction in which the pharmacy is located; and
  - (g) if an applicant engages in compounding, submit the most recent inspection report:
    - (i) conducted within two years before the application for licensure; and
    - (ii)
      - (A) conducted as part of the National Association of Boards of Pharmacy Verified Pharmacy Program; or
      - (B) performed by the state licensing agency of the state in which the applicant is a resident and in accordance with the National Association of Boards of Pharmacy multistate inspection blueprint program.
- (3) Each license issued under this section shall be issued for a single, specific address, and is not transferable or assignable.

Amended by Chapter 384, 2017 General Session

**58-17b-307 Qualification for licensure -- Criminal background checks.**

- (1) An applicant for licensure under this chapter shall:

- (a) submit fingerprint cards in a form acceptable to the division at the time the license application is filed; and
- (b) in accordance with this section and requirements established by rule made in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, consent to a fingerprint background check regarding the application conducted by the:
  - (i) Utah Bureau of Criminal Identification; and
  - (ii) Federal Bureau of Investigation.
- (2) The division shall:
  - (a) in addition to other fees authorized by this chapter, collect from each applicant submitting fingerprints in accordance with this section the fee that the Bureau of Criminal Identification is authorized to collect for the services provided under Section 53-10-108 and the fee charged by the Federal Bureau of Investigation for fingerprint processing for the purpose of obtaining federal criminal history record information;
  - (b) submit from each applicant the fingerprint card and the fees described in Subsection (2)(a) to the Bureau of Criminal Identification; and
  - (c) obtain and retain in division records, a signed waiver approved by the Bureau of Criminal Identification in accordance with Section 53-10-108 for each applicant.
- (3) The Bureau of Criminal Identification shall, in accordance with the requirements of Section 53-10-108:
  - (a) check the fingerprints submitted under Subsection (2)(b) against the applicable state and regional criminal records databases;
  - (b) forward the fingerprints to the Federal Bureau of Investigation for a national criminal history background check; and
  - (c) provide the results from the state, regional, and nationwide criminal history background checks to the division.
- (4) For purposes of conducting the criminal background check required in Subsection (1), the division shall have direct access to criminal background information maintained under Title 53, Chapter 10, Part 2, Bureau of Criminal Identification.
- (5)
  - (a) A new pharmacist, pharmacy intern, or pharmacy technician license issued under this section is conditional, pending completion of the criminal background check.
  - (b) Notwithstanding Title 63G, Chapter 4, Administrative Procedures Act, if the criminal background check required in Subsection (1), discloses the applicant has failed to accurately disclose a criminal history, the license is immediately and automatically revoked upon notice to the licensee by the division.
- (6)
  - (a) A person whose conditional license has been revoked under Subsection (5) is entitled to a postrevocation hearing to challenge the revocation.
  - (b) The division shall conduct a postrevocation hearing in accordance with Title 63G, Chapter 4, Administrative Procedures Act.
- (7) The division may not disseminate outside of the division any criminal history record information that the division obtains from the Bureau of Criminal Identification or the Federal Bureau of Investigation under the criminal background check requirements of this section.

Amended by Chapter 318, 2018 General Session

**58-17b-308 Term of license -- Expiration -- Renewal.**

- (1) Except as provided in Subsection (2), each license issued under this chapter shall be issued in accordance with a two-year renewal cycle established by rule. A renewal period may be extended or shortened by as much as one year to maintain established renewal cycles or to change an established renewal cycle. Each license automatically expires on the expiration date shown on the license unless renewed by the licensee in accordance with Section 58-1-308.
- (2) The duration of a pharmacy intern license may be no longer than:
  - (a) one year for a license issued under Subsection 58-17b-304(7)(b); or
  - (b) five years for a license issued under Subsection 58-17b-304(7)(a).
- (3) A pharmacy intern license issued under this chapter may not be renewed, but may be extended by the division in collaboration with the board.
- (4) As a prerequisite for renewal of a class D pharmacy license of a pharmacy that engages in compounding, a licensee shall submit the most recent inspection report:
  - (a) conducted within two years before the application for renewal; and
  - (b)
    - (i) conducted as part of the National Association of Boards of Pharmacy Verified Pharmacy Program; or
    - (ii) performed by the state licensing agency of the state in which the applicant is a resident and in accordance with the National Association of Boards of Pharmacy multistate inspection blueprint program.

Amended by Chapter 384, 2017 General Session

**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.

Amended by Chapter 207, 2016 General Session

**58-17b-309.6 Exemptions from licensure for research using pharmaceuticals.**

Research using pharmaceuticals, as defined in Section 58-17b-102, is exempt from licensure under Sections 58-17b-301 and 58-17b-302.

Amended by Chapter 181, 2017 General Session

**58-17b-310 Continuing education.**

The division in collaboration with the board may establish by rule continuing education requirements for each classification of licensure under this chapter.



Enacted by Chapter 280, 2004 General Session

## **Part 4 License Denial and Discipline**

### **58-17b-401 Grounds for denial of licensure -- Disciplinary proceedings.**

Grounds for the following action regarding a license issued under this chapter shall be in accordance with Section 58-1-401:

- (1) refusal to issue a license to an applicant;
- (2) refusal to renew the license of a licensee;
- (3) to revoke, suspend, restrict, or place on probation the license of a licensee;
- (4) to issue a public or private reprimand to a licensee;
- (5) to issue cease and desist orders; and
- (6) to issue an administrative fine or citation.

Enacted by Chapter 280, 2004 General Session

## **Part 5 Unlawful and Unprofessional Conduct - Penalties - Enforcement**

### **58-17b-501 Unlawful conduct.**

"Unlawful conduct" includes:

- (1) knowingly preventing or refusing to permit an authorized agent of the division to conduct an inspection pursuant to Section 58-17b-103;
- (2) failing to deliver the license, permit, or certificate to the division upon demand, if it has been revoked, suspended, or refused;
- (3)
  - (a) using the title "pharmacist," "druggist," "pharmacy intern," "pharmacy technician," or a term having similar meaning, except by a person licensed as a pharmacist, pharmacy intern, or pharmacy technician; or
  - (b) conducting or transacting business under a name that contains, as part of that name, the words "drugstore," "pharmacy," "drugs," "medicine store," "medicines," "drug shop," "apothecary," "prescriptions," or a term having a similar meaning, or in any manner advertising, otherwise describing, or referring to the place of the conducted business or profession, unless the place is a pharmacy issued a license by the division, except an establishment selling nonprescription drugs and supplies may display signs bearing the words "packaged drugs," "drug sundries," or "nonprescription drugs," and is not considered to be a pharmacy or drugstore by reason of the display;
- (4) buying, selling, causing to be sold, or offering for sale, a drug or device that bears, or the package bears or originally did bear, the inscription "sample," "not for resale," "for investigational or experimental use only," or other similar words, except when a cost is incurred in the bona fide acquisition of an investigational or experimental drug;
- (5) using to a person's own advantages or revealing to anyone other than the division, board, and its authorized representatives, or to the courts, when relevant to a judicial or administrative

- proceeding under this chapter, information acquired under authority of this chapter or concerning a method of process that is a trade secret;
- (6) procuring or attempting to procure a drug or to have someone else procure or attempt to procure a drug:
    - (a) by fraud, deceit, misrepresentation, or subterfuge;
    - (b) by forgery or alteration of a prescription or a written order;
    - (c) by concealment of a material fact;
    - (d) by use of a false statement in a prescription, chart, order, or report; or
    - (e) by theft;
  - (7) filling, refilling, or advertising the filling or refilling of prescriptions for a consumer or patient residing in this state if the person is not licensed:
    - (a) under this chapter; or
    - (b) in the state from which he is dispensing;
  - (8) requiring an employed pharmacist, pharmacy intern, pharmacy technician, or authorized supportive personnel to engage in conduct in violation of this chapter;
  - (9) being in possession of a prescription drug for an unlawful purpose;
  - (10) dispensing a prescription drug to a person who does not have a prescription from a practitioner, except as permitted under:
    - (a) Title 26, Chapter 55, Opiate Overdose Response Act; or
    - (b) Title 26, Chapter 64, Family Planning Access Act;
  - (11) dispensing a prescription drug to a person who the person dispensing the drug knows or should know is attempting to obtain drugs by fraud or misrepresentation;
  - (12) selling, dispensing, distributing, or otherwise trafficking in prescription drugs when not licensed to do so or when not exempted from licensure; and
  - (13) a person using a prescription drug or controlled substance that was not lawfully prescribed for the person by a practitioner.

Amended by Chapter 295, 2018 General Session

**58-17b-502 Unprofessional conduct.**

"Unprofessional conduct" includes:

- (1) willfully deceiving or attempting to deceive the division, the board, or their agents as to any relevant matter regarding compliance under this chapter;
- (2)
  - (a) except as provided in Subsection (2)(b):
    - (i) paying or offering rebates to practitioners or any other health care providers, or receiving or soliciting rebates from practitioners or any other health care provider; or
    - (ii) paying, offering, receiving, or soliciting compensation in the form of a commission, bonus, rebate, kickback, or split fee arrangement with practitioners or any other health care provider, for the purpose of obtaining referrals.
  - (b) Subsection (2)(a) does not apply to:
    - (i) giving or receiving price discounts based on purchase volume;
    - (ii) passing along pharmaceutical manufacturer's rebates; or
    - (iii) providing compensation for services to a veterinarian.
- (3) misbranding or adulteration of any drug or device or the sale, distribution, or dispensing of any outdated, misbranded, or adulterated drug or device;
- (4) engaging in the sale or purchase of drugs or devices that are samples or packages bearing the inscription "sample" or "not for resale" or similar words or phrases;

- (5) except as provided in Section 58-17b-503 or Part 9, Charitable Prescription Drug Recycling Act, accepting back and redistributing any unused drug, or a part of it, after it has left the premises of any pharmacy, unless the drug is in a unit pack, as defined in Section 58-17b-503, or the manufacturer's sealed container, as defined in rule;
- (6) an act in violation of this chapter committed by a person for any form of compensation if the act is incidental to the person's professional activities, including the activities of a pharmacist, pharmacy intern, or pharmacy technician;
- (7) violating:
  - (a) the federal Controlled Substances Act, Title II, P.L. 91-513;
  - (b) Title 58, Chapter 37, Utah Controlled Substances Act; or
  - (c) rules or regulations adopted under either act;
- (8) requiring or permitting pharmacy interns or technicians to engage in activities outside the scope of practice for their respective license classifications, as defined in this chapter and division rules made in collaboration with the board, or beyond their scope of training and ability;
- (9) administering:
  - (a) without appropriate training, as defined by rule;
  - (b) without a physician's order, when one is required by law; and
  - (c) in conflict with a practitioner's written guidelines or written protocol for administering;
- (10) disclosing confidential patient information in violation of the provisions of the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936, as amended, or other applicable law;
- (11) engaging in the practice of pharmacy without a licensed pharmacist designated as the pharmacist-in-charge;
- (12) failing to report to the division any adverse action taken by another licensing jurisdiction, government agency, law enforcement agency, or court for conduct that in substance would be considered unprofessional conduct under this section;
- (13) as a pharmacist or pharmacy intern, compounding a prescription drug in a dosage form which is regularly and commonly available from a manufacturer in quantities and strengths prescribed by a practitioner; and
- (14) failing to act in accordance with Title 26, Chapter 64, Family Planning Access Act, when dispensing a self-administered hormonal contraceptive under a standing order.

Amended by Chapter 295, 2018 General Session

**58-17b-503 Exception to unprofessional conduct.**

- (1) For purposes of this section:
  - (a) "Licensed intermediate care facility for people with an intellectual disability" means an intermediate care facility for people with an intellectual disability that is licensed as a nursing care facility or a small health care facility under Title 26, Chapter 21, Health Care Facility Licensing and Inspection Act.
  - (b) "Nursing care facility" means the same as that term is defined in Section 26-21-2.
  - (c) "Unit pack" means a tamper-resistant nonreusable single-dose single-drug package with identification that indicates the lot number and expiration date for the drug.
- (2) A pharmacist may:
  - (a) accept and redistribute an unused drug under Part 9, Charitable Prescription Drug Recycling Act; or
  - (b) accept back and redistribute any unused drug, or a part of it, after it has left the premises of the pharmacy if:

- (i) the drug was prescribed to a patient in a nursing care facility, licensed intermediate care facility for people with an intellectual disability, or state prison facility, county jail, or state hospital;
- (ii) the drug was stored under the supervision of a licensed health care provider according to manufacturer recommendations;
- (iii) the drug is in a unit pack or in the manufacturer's sealed container;
- (iv) the drug was returned to the original dispensing pharmacy;
- (v) the drug was initially dispensed by a licensed pharmacist or licensed pharmacy intern; and
- (vi) accepting back and redistributing of the drug complies with federal Food and Drug Administration and Drug Enforcement Administration regulations.

Amended by Chapter 405, 2016 General Session

**58-17b-504 Penalty for unlawful or unprofessional conduct -- Fines -- Citations.**

- (1) Any person who violates any of the unlawful conduct provisions of Subsection 58-1-501(1)(a)(i) and Subsections 58-17b-501(7) and (11) is guilty of a third degree felony.
- (2) Any person who violates any of the unlawful conduct provisions of Subsection 58-1-501(1)(a)(ii), Subsections 58-1-501(1)(b) through (e), and Section 58-17b-501, except Subsections 58-17b-501(7) and (11), is guilty of a class A misdemeanor.
- (3)
  - (a) Subject to Subsection (5) and in accordance with Section 58-17b-401, for acts of unprofessional or unlawful conduct, the division may:
    - (i) assess administrative penalties; and
    - (ii) take any other appropriate administrative action.
  - (b) An administrative penalty imposed pursuant to this section shall be deposited in the General Fund as a dedicated credit to be used by the division for pharmacy licensee education and enforcement as provided in Section 58-17b-505.
- (4) If a licensee has been convicted of violating Section 58-17b-501 prior to an administrative finding of a violation of the same section, the licensee may not be assessed an administrative fine under this chapter for the same offense for which the conviction was obtained.
- (5)
  - (a) If upon inspection or investigation, the division concludes that a person has violated the provisions of Section 58-17b-501 or 58-17b-502, Chapter 37, Utah Controlled Substances Act, Chapter 37f, Controlled Substance Database Act, Chapter 1, Division of Occupational and Professional Licensing Act, or any rule or order issued with respect to these provisions, and that disciplinary action is appropriate, the director or the director's designee from within the division shall promptly issue a citation to the person according to this chapter and any pertinent rules, attempt to negotiate a stipulated settlement, or notify the person to appear before an adjudicative proceeding conducted under Title 63G, Chapter 4, Administrative Procedures Act.
  - (b) Any person who is in violation of the provisions of Section 58-17b-501 or 58-17b-502, Chapter 37, Utah Controlled Substances Act, Chapter 37f, Controlled Substance Database Act, Chapter 1, Division of Occupational and Professional Licensing Act, or any rule or order issued with respect to these provisions, as evidenced by an uncontested citation, a stipulated settlement, or a finding of violation in an adjudicative proceeding, may be assessed a fine pursuant to this Subsection (5) of up to \$10,000 per single violation or up to \$2,000 per day of ongoing violation, whichever is greater, in accordance with a fine schedule established by rule, and may, in addition to or in lieu of, be ordered to cease and desist from violating the

provisions of Section 58-17b-501 or 58-17b-502, Chapter 37, Utah Controlled Substances Act, Chapter 1, Division of Occupational and Professional Licensing Act, or any rule or order issued with respect to these provisions.

- (c) Except for an administrative fine and a cease and desist order, the licensure sanctions cited in Section 58-17b-401 may not be assessed through a citation.
  - (d) Each citation shall be in writing and specifically describe with particularity the nature of the violation, including a reference to the provision of the chapter, rule, or order alleged to have been violated. The citation shall clearly state that the recipient must notify the division in writing within 20 calendar days of service of the citation in order to contest the citation at a hearing conducted under Title 63G, Chapter 4, Administrative Procedures Act. The citation shall clearly explain the consequences of failure to timely contest the citation or to make payment of any fines assessed by the citation within the time specified in the citation.
  - (e) Each citation issued under this section, or a copy of each citation, may be served upon any person upon whom a summons may be served:
    - (i) in accordance with the Utah Rules of Civil Procedure;
    - (ii) personally or upon the person's agent by a division investigator or by any person specially designated by the director; or
    - (iii) by mail.
  - (f) If within 20 calendar days from the service of a citation, the person to whom the citation was issued fails to request a hearing to contest the citation, the citation becomes the final order of the division and is not subject to further agency review. The period to contest the citation may be extended by the division for cause.
  - (g) The division may refuse to issue or renew, suspend, revoke, or place on probation the license of a licensee who fails to comply with the citation after it becomes final.
  - (h) The failure of an applicant for licensure to comply with a citation after it becomes final is a ground for denial of license.
  - (i) No citation may be issued under this section after the expiration of six months following the occurrence of any violation.
- (6)
- (a) The director may collect a penalty that is not paid by:
    - (i) referring the matter to a collection agency; or
    - (ii) bringing an action in the district court of the county where the person against whom the penalty is imposed resides or in the county where the office of the director is located.
  - (b) A county attorney or the attorney general of the state shall provide legal assistance and advice to the director in an action to collect a penalty.
  - (c) A court shall award reasonable attorney fees and costs to the prevailing party in an action brought by the division to collect a penalty.

Amended by Chapter 318, 2018 General Session

**58-17b-505 Educational and enforcement fund.**

- (1) The director may use the money collected pursuant to Section 58-17b-504 for the following purposes:
  - (a) education and training of licensees under this chapter;
  - (b) enforcement of this chapter by:
    - (i) investigating unprofessional or unlawful conduct;
    - (ii) providing legal representation to the division when legal action is taken against a person engaging in unprofessional or unlawful conduct;

- (iii) monitoring compliance of renewal requirement; and
  - (iv) education and training of division staff and board members.
- (2) All funding for the purposes listed in Subsection (1) is nonlapsing.
- (3) Any penalty which is not paid may be collected by the director by either referring the matter to a collection agency or bringing an action in the district court of the county in which the person against whom the penalty is imposed resides or in the county where the office of the director is located.
- (4) Any county attorney or the attorney general of the state is to provide legal assistance and advice to the director in any action to collect the penalty. In any action brought to enforce the provisions of this section, reasonable attorney's fees and costs shall be awarded in which the person against whom the penalty is imposed resides or in the county where the office of the director is located.

Enacted by Chapter 280, 2004 General Session

**58-17b-506 Petitioning for reinstatement of licensure.**

Any person whose license to practice pharmacy in this state has been revoked, suspended, or surrendered voluntarily or by action of the division, shall have the right at reasonable intervals, to petition the division for reinstatement of such license. Such petition shall be made in writing and in the form prescribed by the division. Upon investigation and hearing, the division may, in its discretion, grant or deny such petition, or it may modify its original finding to reflect any circumstances that have changed sufficiently to warrant such modifications. The division, also at its discretion, may require such person to pass an examination or examinations for re-entry into the practice of pharmacy.

Enacted by Chapter 280, 2004 General Session

**58-17b-507 Opiate antagonist -- Immunity from liability -- Exclusion from unlawful or unprofessional conduct.**

- (1) As used in this section:
- (a) "Opiate antagonist" means the same as that term is defined in Section 26-55-102.
  - (b) "Opiate-related drug overdose event" means the same as that term is defined in Section 26-55-102.
- (2) A person licensed under this chapter that dispenses an opiate antagonist to an individual with a prescription for an opiate antagonist, to an overdose outreach provider with a prescription for an opiate antagonist, or pursuant to a standing prescription drug order issued in accordance with Subsection 26-55-105(2) is not liable for any civil damages resulting from the outcomes of the eventual administration of the opiate antagonist to an individual who another individual believes is experiencing an opiate-related drug overdose event.
- (3) The provisions of this section and Title 26, Chapter 55, Opiate Overdose Response Act, do not establish a duty or standard of care in the prescribing, dispensing, or administration of an opiate antagonist.
- (4) It is not unprofessional conduct or unlawful conduct for a licensee under this chapter to dispense an opiate antagonist to a person, including a person described in Subsections 26-55-107(1)(a)(i)(A) through (1)(a)(i)(F), on behalf of an individual if the person obtaining the opiate antagonist has a prescription for the opiate antagonist from a licensed prescriber or the opiate antagonist is dispensed pursuant to a standing prescription drug order issued in accordance with Subsection 26-55-105(2).

- (5) It is not unprofessional conduct or unlawful conduct for a licensee under this chapter to dispense an opiate antagonist to an overdose outreach provider if the overdose outreach provider has a prescription for the opiate antagonist from a licensed prescriber issued pursuant to Subsection 26-55-104(2)(a)(iii).

Amended by Chapter 202, 2016 General Session, (Coordination Clause)

Amended by Chapter 202, 2016 General Session

Amended by Chapter 207, 2016 General Session

Amended by Chapter 208, 2016 General Session

## **Part 6**

### **Regulation of the Practice of Pharmacy Operating Standards**

#### **58-17b-601 General operating standards.**

- (1)
- (a) The division shall make rules relating to the operations and conduct of facilities, individuals, and entities which are regulated under this chapter, to protect the public health, safety, and welfare.
  - (b) The rules shall be consistent with the regulations of the Federal Food and Drug Administration and Drug Enforcement Administration, this chapter, and all other laws relating to activities and persons regulated under this chapter.
- (2)
- (a) This chapter does not prevent, restrict, or in any other manner interfere with the sale of nonprescription drugs.
  - (b) The division may not make any rules under this chapter that require nonprescription drugs to be sold by a licensed pharmacist or only in a pharmaceutical facility.
  - (c) The sale or distribution of nonprescription drugs does not constitute the practice of pharmacy.

Enacted by Chapter 280, 2004 General Session

#### **58-17b-602 Prescription orders -- Information required -- Alteration -- Labels -- Signatures -- Dispensing in pharmacies.**

- (1) Except as provided in Section 58-1-501.3, the minimum information that shall be included in a prescription order, and that may be defined by rule, is:
- (a) the prescriber's name, address, and telephone number, and, if the order is for a controlled substance, the patient's age and the prescriber's DEA number;
  - (b) the patient's name and address or, in the case of an animal, the name of the owner and species of the animal;
  - (c) the date of issuance;
  - (d) the name of the medication or device prescribed and dispensing instructions, if necessary;
  - (e) the directions, if appropriate, for the use of the prescription by the patient or animal and any refill, special labeling, or other instructions;
  - (f) the prescriber's signature if the prescription order is written;
  - (g) if the order is an electronically transmitted prescription order, the prescribing practitioner's electronic signature; and

- (h) if the order is a hard copy prescription order generated from electronic media, the prescribing practitioner's electronic or manual signature.
- (2) The requirement of Subsection (1)(a) does not apply to prescription orders dispensed for inpatients by hospital pharmacies if the prescriber is a current member of the hospital staff and the prescription order is on file in the patient's medical record.
- (3) Unless it is for a Schedule II controlled substance, a prescription order may be dispensed by a pharmacist or pharmacy intern upon an oral prescription of a practitioner only if the oral prescription is promptly reduced to writing.
- (4)
  - (a) Except as provided under Subsection (4)(b), a pharmacist or pharmacy intern may not dispense or compound any prescription of a practitioner if the prescription shows evidence of alteration, erasure, or addition by any person other than the person writing the prescription.
  - (b) A pharmacist or pharmacy intern dispensing or compounding a prescription may alter or make additions to the prescription after receiving permission of the prescriber and may make entries or additions on the prescription required by law or necessitated in the compounding and dispensing procedures.
- (5)
  - (a) Each drug dispensed shall have a label securely affixed to the container indicating the following minimum information:
    - (i) the name, address, and telephone number of the pharmacy;
    - (ii) the serial number of the prescription as assigned by the dispensing pharmacy;
    - (iii) the filling date of the prescription or its last dispensing date;
    - (iv) the name of the patient, or in the case of an animal, the name of the owner and species of the animal;
    - (v) the name of the prescriber;
    - (vi) the directions for use and cautionary statements, if any, which are contained in the prescription order or are needed;
    - (vii) except as provided in Subsection (7), the trade, generic, or chemical name, amount dispensed and the strength of dosage form, but if multiple ingredient products with established proprietary or nonproprietary names are prescribed, those products' names may be used; and
    - (viii) the beyond use date.
  - (b) The requirements described in Subsections (5)(a)(i) through (vi) do not apply to a label on the container of a drug that a health care provider administers to a patient at:
    - (i) a pharmaceutical administration facility; or
    - (ii) a hospital licensed under Title 26, Chapter 21, Health Care Facility Licensing and Inspection Act.
- (6) A hospital pharmacy that dispenses a prescription drug that is packaged in a multidose container to a hospital patient may provide the drug in the multidose container to the patient when the patient is discharged from the hospital if:
  - (a) the pharmacy receives a discharge order for the patient; and
  - (b) the pharmacy labels the drug with the:
    - (i) patient's name;
    - (ii) drug's name and strength;
    - (iii) directions for use of the drug, if applicable; and
    - (iv) pharmacy's name and phone number.



- (7) If the prescriber specifically indicates the name of the prescription product should not appear on the label, then any of the trade, generic, chemical, established proprietary, and established nonproprietary names and the strength of dosage form may not be included.
- (8) Prescribers are encouraged to include on prescription labels the information described in Section 58-17b-602.5 in accordance with the provisions of that section.
- (9) A pharmacy may only deliver a prescription drug to a patient or a patient's agent:
  - (a) in person at the pharmacy; or
  - (b) via the United States Postal Service, a licensed common carrier, or supportive personnel, if the pharmacy takes reasonable precautions to ensure the prescription drug is:
    - (i) delivered to the patient or patient's agent; or
    - (ii) returned to the pharmacy.

Amended by Chapter 384, 2017 General Session

**58-17b-602.5 Information on prescription labels -- Education outreach.**

The division, in order to assist emergency responders in quickly determining the physical condition of a patient at the scene of an emergency, as well as for the benefit of physicians and consumers, shall:

- (1) provide information on the pharmacy licensing website recommending that prescribers, pharmacists, and pharmacy interns include information on the label of a drug dispensed under Section 58-17b-602 describing the condition the prescription is meant to treat; and
- (2) as part of the website information, specify that information described in Subsection (1) should not be included on the label if the prescriber or patient indicates that the information may not be included on the label.

Enacted by Chapter 79, 2013 General Session

**58-17b-603 Identification of pharmacy personnel.**

- (1) All individuals employed in a pharmacy facility having any contact with the public or patients receiving services from that pharmacy facility shall wear on their person a clearly visible and readable identification showing the individual's name and position.
- (2) When communicating by any means, written, verbal, or electronic, pharmacy personnel must identify themselves as to licensure classification.

Enacted by Chapter 280, 2004 General Session

**58-17b-604 Medication profiles.**

- (1) Each pharmacy shall establish a medication profile system for pharmacy patients according to the standards established by division rules made in collaboration with the board. The rules shall indicate the method for recording all prescription information.
- (2) The pharmacy shall maintain the medication profile for any pharmacy patient who expresses a desire for that professional service.
- (3) The pharmacy may charge an appropriate professional fee for this service and for copying or providing information in the medication profile to another authorized person.
- (4) A pharmacist, pharmacy intern, or pharmacy technician may not release or discuss the information contained in a prescription or patient's medication profile to anyone except:
  - (a) the pharmacy patient in person or the pharmacy patient's legal guardian or designee;
  - (b) a lawfully authorized federal, state, or local drug enforcement officer;

- (c) a third party payment program administered under terms authorized by the pharmacy patient;
- (d) a pharmacist, pharmacy intern, or pharmacy technician providing pharmacy services to the patient or a prescribing practitioner providing professional services to the patient;
- (e) another pharmacist, pharmacy intern, pharmacy technician, or prescribing practitioner to whom the patient has requested a prescription transfer; or
- (f) the pharmacy patient's attorney, after the presentation of a written authorization signed by the:
  - (i) patient, before a notary public;
  - (ii) parent or lawful guardian, if the patient is a minor;
  - (iii) lawful guardian, if the patient is incompetent; or
  - (iv) personal representative, if the patient is deceased.

Enacted by Chapter 280, 2004 General Session

**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 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.
- (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) Failure of a licensed medical practitioner to specify that no substitution is authorized does not constitute evidence of negligence.

Amended by Chapter 423, 2013 General Session

**58-17b-605.5 Interchangeable biological products.**

- (1) For the purposes of this section:
  - (a) "Biological product" means the same as that term is defined in 42 U.S.C. Sec. 262.
  - (b) "Interchangeable biological product" means a biological product that the federal Food and Drug Administration:
    - (i) has:
      - (A) licensed; and

- (B) determined meets the standards for interchangeability pursuant to 42 U.S.C. Sec. 262(k)(4); or
  - (ii) has determined is therapeutically equivalent as set forth in the latest edition of or supplement to the federal Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations.
- (2) A pharmacist or pharmacy intern dispensing a prescription order for a specific biological product by brand or proprietary name may substitute an interchangeable biological product for the prescribed biological product only if:
- (a) the purchaser specifically requests or consents to the substitute of an interchangeable biological product;
  - (b) the interchangeable biological product is permitted to move in interstate commerce;
  - (c) the pharmacist or pharmacy intern counsels the patient on the use and the expected response to the prescribed biological product, whether a substitute or not, and the substitution is not otherwise prohibited by this chapter;
  - (d) the prescribing practitioner has not prohibited the substitution of an interchangeable biological product for the prescribed biological product, as provided in Subsection (6); and
  - (e) the substitution is not otherwise prohibited by law.
- (3) Each out-of-state mail service pharmacy dispensing an interchangeable biological product as a substitute for another biological product into this state shall:
- (a) notify the patient of the substitution either by telephone or in writing; and
  - (b) comply with the requirements of this chapter with respect to an interchangeable biological product substituted for another biological product, including labeling and record keeping.
- (4) Pharmacists or pharmacy interns may not substitute without the prescriber's authorization biological product prescriptions unless the product has been determined by the United States Food and Drug Administration to be interchangeable with the prescribed biological product.
- (5) A pharmacist or pharmacy intern who dispenses a prescription with an interchangeable biological product under this section assumes no greater liability than would be incurred had the pharmacist or pharmacy intern dispensed the prescription with the biological product prescribed.
- (6)
- (a) If, in the opinion of the prescribing practitioner, it is in the best interest of the patient that an interchangeable biological product not be substituted for a prescribed biological product, the practitioner may prohibit a substitution either by writing "dispense as written" or by signing in the appropriate space where two lines have been preprinted on a prescription order and captioned "dispense as written" or "substitution permitted."
  - (b)
    - (i) If the prescription is communicated orally by the prescribing practitioner to the pharmacist or pharmacy intern, the practitioner shall direct the prohibition or substitution.
    - (ii) The pharmacist or pharmacy intern shall make a written note of the practitioner's direction by writing 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 an interchangeable biological product for a prescribed biological product shall communicate the substitution to the purchaser. The interchangeable biological product container shall be labeled with the name of the interchangeable biological product dispensed, and the pharmacist, pharmacy intern, or pharmacy technician shall indicate on the file copy of the prescription both the name of the prescribed biological product and the name of the interchangeable biological product dispensed in its place.

- (8) Within five business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall make an entry of the specific product provided to the patient, including the name of the product and the manufacturer. The communication shall be conveyed by making an entry into an interoperable electronic medical records system, through an electronic prescribing technology, a pharmacy benefit management system, or a pharmacy record that is electronically accessible by the prescriber. Entry into an electronic records system as described in this Subsection (8) is presumed to provide notice to the prescriber. Otherwise, the pharmacist shall communicate the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission, or other prevailing means, provided that communication shall not be required where:
- (a) there is no FDA-approved interchangeable biological product for the product prescribed;
  - (b) a refill prescription is not changed from the product dispensed on the prior filling of the prescription; or
  - (c) the product is paid for using cash or cash equivalent.

Amended by Chapter 266, 2015 General Session

**58-17b-606 Restrictive drug formulary prohibited.**

- (1) As used in this section:
- (a) "Generic form" means a prescription drug that is available in generic form and has an A rating in the United States Pharmacopeia and Drug Index.
  - (b) "Legend drug" has the same meaning as prescription drug.
  - (c) "Restrictive drug formulary" means a list of legend drugs, other than drugs for cosmetic purposes, that are prohibited by the Department of Health from dispensation, but are approved by the Federal Food and Drug Administration.
- (2) A practitioner may prescribe legend drugs in accordance with this chapter that, in his professional judgment and within the lawful scope of his practice, he considers appropriate for the diagnosis and treatment of his patient.
- (3) Except as provided in Subsection (4), the Department of Health may not maintain a restrictive drug formulary that restricts a physician's ability to treat a patient with a legend drug that has been approved and designated as safe and effective by the Federal Food and Drug Administration, except for drugs for cosmetic purposes.
- (4) When a multisource legend drug is available in the generic form, the Department of Health may only reimburse for the generic form of the drug unless the treating physician demonstrates to the Department of Health a medical necessity for dispensing the nongeneric, brand-name legend drug.
- (5) The Department of Health pharmacists may override the generic mandate provisions of Subsection (4) if a financial benefit will accrue to the state.
- (6) This section does not affect the state's ability to exercise the exclusion options available under the Federal Omnibus Budget Reconciliation Act of 1990.

Amended by Chapter 101, 2010 General Session

**58-17b-607 Drug substitution is not the practice of medicine -- Other causes of action not denied.**

- (1) The substitution of any drug by a licensed pharmacist or pharmacy intern under this chapter does not constitute the practice of medicine.

- (2) This chapter may not be construed to deny any individual a cause of action against a pharmacist, pharmacy intern, or his employer for violations of this chapter, including failure to observe accepted standards of care of the pharmaceutical profession.

Enacted by Chapter 280, 2004 General Session

**58-17b-608 Emergency refills.**

- (1) In the interest of the patient's health, a pharmacist or pharmacy intern may, in an emergency, refill a prescription for a patient, but only if the prescribing practitioner is not available promptly to authorize the refill and only if in the professional judgment of the pharmacist or pharmacy intern the prescription should be refilled.
- (2) Only sufficient medication as necessary in the emergency may be furnished by the pharmacist or pharmacy intern, not to exceed a three-day supply.
- (3) The practitioner shall be contacted as soon as possible for further instructions concerning the emergency.

Enacted by Chapter 280, 2004 General Session

**58-17b-608.1 Refills of legend drug prescriptions.**

- (1) If a prescription for a legend drug includes authorization for one or more refills, a pharmacist or pharmacy intern may dispense one or more of the refills at the time the drug is dispensed, if:
  - (a) the drug is not a controlled substance;
  - (b) the prescription does not include "Dispense quantity written," or some other notation having similar meaning;
  - (c) the total dosage units dispensed, including the units for both the prescription and any refills, do not exceed a 100-day supply; and
  - (d) in the professional judgment of the pharmacist or pharmacy intern, the refill or refills should be dispensed at the time the prescription is dispensed.
- (2) A pharmacist or pharmacy intern may dispense a refill of a prescription for a liquid legend drug administered to the eye once an amount of time has passed after which a patient should have used 70% of the dosage units of the drug according to a practitioner's instructions.

Amended by Chapter 386, 2014 General Session

**58-17b-609 Limitation on prescriptions and refills -- Controlled Substances Act not affected -- Legend drugs.**

- (1) Except as provided in Section 58-16a-102, a prescription for any prescription drug or device may not be dispensed after one year from the date it was initiated except as otherwise provided in Chapter 37, Utah Controlled Substances Act.
- (2) A prescription authorized to be refilled may not be refilled after one year from the original issue date.
- (3) A practitioner may not be prohibited from issuing a new prescription for the same drug orally, in writing, or by electronic transmission.
- (4) Nothing in this chapter affects Chapter 37, Utah Controlled Substances Act.
- (5) A prescription for a legend drug written by a licensed prescribing practitioner in another state may be filled or refilled by a pharmacist or pharmacy intern in this state if the pharmacist or pharmacy intern verifies that the prescription is valid.

Amended by Chapter 160, 2005 General Session

**58-17b-610 Patients' immediate needs -- Dispensing drug samples.**

- (1) This chapter may not be construed to prevent the personal administration of drugs or medicines by practitioners licensed to prescribe in order to supply the immediate needs of the practitioner's patients.
- (2) Immediate need for a patient includes giving out drug samples that:
  - (a) are not Schedule II drugs, opioids, or Benzodiazepines;
  - (b) are prepackaged by the original manufacturer;
  - (c) are provided to the prescribing practitioner free of charge and provided to the patient free of any direct or indirect charge;
  - (d) do not exceed a 30-day supply for:
    - (i) controlled substances; or
    - (ii) non-controlled substances, unless a prescribing practitioner documents that providing more than a 30-day supply is medically necessary; and
  - (e)
    - (i) are marked on the immediate container to indicate that the drug is a sample; or
    - (ii) are recorded in the patient's chart with the name and number of samples provided.
- (3) A prescribing practitioner who provides samples for a patient shall comply with Subsection (2).

Amended by Chapter 320, 2012 General Session

**58-17b-610.5 Dispensing in emergency department -- Patient's immediate need.**

- (1) The division shall adopt administrative rules in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, in consultation with hospital pharmacies and the boards of practitioners authorized to prescribe prescription drugs to establish guidelines under which a practitioner may dispense prescription drugs to a patient in a hospital emergency department if:
  - (a) the hospital pharmacy is closed;
  - (b) in the professional judgment of the practitioner, dispensing the drug is necessary for the patient's immediate needs; and
  - (c) dispensing the prescription drug meets protocols established by the hospital pharmacy.
- (2) A practitioner in an emergency department may dispense a prescription drug in accordance with Subsection (1).

Amended by Chapter 238, 2016 General Session

**58-17b-610.6 Hospital pharmacy dispensing prescription drugs to patients at discharge.**

- (1) The division shall make rules, in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, in consultation with hospital pharmacies, to establish guidelines under which a hospital pharmacy may dispense a limited supply of a prescription drug to an individual who is no longer a patient in the hospital setting if:
  - (a) the individual is discharged from the hospital on the same day that the hospital pharmacy dispenses the prescription drug to the individual;
  - (b) the prescription drug relates to the reason for which the individual was a patient at the hospital before being discharged;
  - (c) the class A pharmacy with which the patient has an established pharmacy-patient relationship is not open at the time of the patient's discharge;
  - (d) the hospital pharmacy dispenses a quantity of the prescription drug that is the lesser of:

- (i) a 72-hour supply; or
  - (ii) an adequate amount to treat the discharged patient through the first day on which the pharmacy described in Subsection (1)(c) is open after the patient's discharge from the hospital; and
  - (e) dispensing the prescription drug complies with protocols established by the hospital pharmacy.
- (2) A hospital pharmacy may dispense a prescription drug in accordance with rules made under Subsection (1).

Enacted by Chapter 44, 2017 General Session

**58-17b-610.7 Partial filling of a Schedule II controlled substance prescription.**

- (1) For purposes of this section, "Schedule II controlled substance" means a substance classified as a Schedule II controlled substance by the federal Controlled Substances Act, Title II, Pub. L. No. 91-513 et seq., or Section 58-37-4.
- (2) A prescription for a Schedule II controlled substance for a patient in a long-term care facility or a patient with a terminal illness may be partially filled in accordance with federal law.
- (3) A prescription for a Schedule II controlled substance for a patient other than a patient described in Subsection (2) may be partially filled:
- (a) in accordance with federal law and rules made under Subsection (5); and
  - (b) at the request of the practitioner who issued the prescription, or the patient.
- (4) For purposes of Subsection (3), "partially filled" means that less than the full amount of the prescription is dispensed.
- (5) For purposes of Subsection (3), the division shall make rules in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act:
- (a) specifying how to record the date, quantity supplied, and quantity remaining of a prescription partially filled under Subsection (3); and
  - (b) otherwise necessary for the implementation of Subsections (2) and (3).

Enacted by Chapter 66, 2017 General Session

**58-17b-611 Pharmacy records.**

- (1) Each pharmacy shall maintain its prescription files and other records in accordance with this chapter, division rules made in collaboration with the board, and federal regulations.
- (2) Each out-of-state mail service pharmacy shall maintain its prescription files in accordance with applicable rules or regulations of the state in which its facilities are located and federal regulations.

Enacted by Chapter 280, 2004 General Session

**58-17b-612 Supervision -- Pharmacist-in-charge.**

- (1)
- (a) Any pharmacy, except a wholesaler, distributor, out-of-state mail service pharmacy, or class E pharmacy, shall be under the general supervision of at least one pharmacist licensed to practice in Utah. One pharmacist licensed in Utah shall be designated as the pharmacist-in-charge, whose responsibility it is to oversee the operation of the pharmacy.



- (b) Notwithstanding Subsection 58-17b-102(68), a supervising pharmacist does not have to be in the pharmacy or care facility but shall be available via a telepharmacy system for immediate contact with the supervised pharmacy technician or pharmacy intern if:
  - (i) the pharmacy is located in:
    - (A) a remote rural hospital, as defined in Section 26-21-13.6; or
    - (B) a clinic located in a remote rural county with less than 20 people per square mile;
  - (ii) the supervising pharmacist described in Subsection (1)(a) is not available; and
  - (iii) the telepharmacy system maintains records and files quarterly reports as required by division rule to assure that patient safety is not compromised.
- (2) Each out-of-state mail service pharmacy shall designate and identify to the division a pharmacist holding a current license in good standing issued by the state in which the pharmacy is located and who serves as the pharmacist-in-charge for all purposes under this chapter.

Amended by Chapter 72, 2014 General Session

**58-17b-613 Patient counseling.**

- (1) A pharmacy shall verbally offer to counsel a patient or a patient's agent in a personal face-to-face discussion regarding each prescription drug dispensed, if the patient or patient's agent:
  - (a) delivers the prescription in person to the pharmacist or pharmacy intern; or
  - (b) receives the drug in person at the time it is dispensed at the pharmacy facility.
- (2) A pharmacist or pharmacy intern at a pharmacy that receives a prescription from a patient by means other than personal delivery, and that dispenses prescription drugs to the patient by means other than personal delivery, shall:
  - (a) provide patient counseling to a patient regarding each prescription drug the pharmacy dispenses; and
  - (b) provide each patient with a toll-free telephone number by which the patient can contact a pharmacist or pharmacy intern at the pharmacy for counseling.
- (3) Notwithstanding the provisions of Subsections (1) and (2), a pharmacist or a pharmacy intern may provide patient counseling to an individual under the jurisdiction of the Utah Department of Corrections or a county detention facility via a written, telephone, or electronic communication.

Amended by Chapter 336, 2015 General Session

**58-17b-614 Notification.**

- (1) A pharmacy shall report in writing to the division not later than 10 business days before the date of:
  - (a) a permanent closure of the pharmacy facility;
  - (b) a change of name or ownership of the pharmacy facility;
  - (c) a change of location of the pharmacy facility;
  - (d) a sale or transfer of any controlled substance as a result of the permanent closing or change of ownership of the pharmacy facility;
  - (e) any matter or occurrence that the board requires by rule to be reported;
  - (f) a final administrative disciplinary order against the pharmacy license holder by the regulatory or licensing agency of the state in which the pharmacy is located if the pharmacy is a class D pharmacy; or

- (g) a final order against a pharmacist who is designated as the pharmacist-in-charge of the pharmacy by the regulatory or licensing agency of the state in which the pharmacy is located if the pharmacy is a class D pharmacy.
- (2) A pharmacy 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 as defined by rule.
- (3) A reporting pharmacy shall maintain a copy of any notification required by this section for two years and make a copy available for inspection.

Amended by Chapter 279, 2007 General Session

**58-17b-615 Sale of prescription drugs not in normal course of business.**

- (1) As used in this section, "seller" means a person selling prescription drugs or devices owned or lawfully controlled by him, or a party arranging for the sale of prescription drugs or devices owned by or lawfully controlled by another person, including salvage companies that acquire prescription drugs and devices from, or act as an agent or representative for freight haulers and forwarders.
- (2) Any sale of prescription drugs in bankruptcy, at public auction, at freight liquidation sales, or any other sale of prescription drugs other than in the normal course of business or practice shall comply with the following:
  - (a) a seller of prescription drugs shall be licensed by the division as a prescription drug distributor or wholesaler with a regular license, or a temporary license for that sale only, before engaging in the sale of any prescription drugs; and
  - (b) a person licensed as a pharmacy under this chapter may not acquire by purchase or other means prescription drugs or devices outside the normal course of business within the meaning of this section unless:
    - (i) the prescription drugs or devices are accompanied by a certificate signed by a licensed pharmacist employed or retained by the seller, as required in Subsection (3), attesting that the prescription drugs or devices have not been adversely affected by circumstances relating to their transportation, storage, or distribution; and
    - (ii) the licensee acquiring the prescription drugs or devices employs a qualified pharmacist who is responsible for determining that all prescription drugs being acquired do not pose any threat to the public welfare if introduced into commerce than would be presented by the acquisition of those prescription drugs and devices in the normal course of business through established channels of prescription drug distribution.
- (3) A seller of prescription drugs outside the normal course of business shall retain the services of a qualified pharmacist licensed to practice in the state to serve as either an employee or independent consultant to determine if the:
  - (a) prescription drugs and devices to be offered for sale have been transported, stored, and distributed in accordance with applicable federal, state, and local laws; and
  - (b) condition of the prescription drugs and devices to be offered for sale has been adversely affected by the circumstances of transportation, storage, or distribution.
- (4) The written notice provided to the division prior to the sale of any prescription drugs or devices under this section shall contain written verification of the pharmacist retained by the seller, stating the drugs or devices offered for sale have not been adversely affected by the circumstances of transportation, storage, or distribution.

- (5) A pharmacist employed by a seller under Subsection (3) or a pharmacy, distributor, or wholesaler for whom that pharmacist may be employed or in which he may have an interest, may not purchase any prescription drugs or devices from the seller for which that pharmacist has provided verification regarding the drugs or devices.

Enacted by Chapter 280, 2004 General Session

**58-17b-616 Drug stock sales -- Labeling.**

- (1) A manufacturer, wholesaler, or distributor of prescription drugs may not sell or give any prescription drug to any person, unless the prescription drug stock container bears a label containing information as defined by rule, the name and place of business of the manufacturer of the finished dosage form of the drug, and if different from the manufacturer, the name and place of business of the packer or distributor.
- (2) Each tablet or capsule shall be marked with an identification code or monogram, unless waived by the division.
- (3) Each stock package shall bear an expiration date and lot number.

Enacted by Chapter 280, 2004 General Session

**58-17b-617 Limitations on distribution of prescription drugs by pharmaceutical manufacturers or wholesalers.**

- (1) A pharmaceutical manufacturer or pharmaceutical wholesaler may not provide a prescription drug to any person, except as defined by rule.
- (2)
  - (a) Prescription drugs that are not controlled substances may be:
    - (i) distributed or provided as drug samples to a person licensed within the state to sell, prescribe, administer, or conduct research with legend drugs; and
    - (ii) supplied in connection with a manufacturer's patient assistance program to be distributed to qualifying patients enrolled in the program.
  - (b) Controlled substance prescription drugs may be sold or provided only:
    - (i) upon the issuance of an order or request by a person appropriately licensed under state and federal law to sell, prescribe, administer, or conduct research with prescription drugs; and
    - (ii) upon the establishment of documents in the possession of the manufacturer or distributor recording the purchaser, type of drug, quantity of drug, date of shipment, and date of delivery.
- (3) Purchasers or those in receipt of drugs under this section shall maintain records in accordance with federal and state laws regarding controlled substances.

Enacted by Chapter 280, 2004 General Session

**58-17b-618 Compliance with state and federal laws.**

The entities licensed under Sections 58-17b-301 and 58-17b-302 shall comply with all state and federal laws and regulations relating to the practice of pharmacy.

Enacted by Chapter 280, 2004 General Session

**58-17b-619 Third party payors -- Health maintenance organizations.**

- (1) Any third party payor for pharmaceutical services within the state, or its agent or contractor may not require any pharmacy patient to obtain prescription drug benefits from a specific out-of-state pharmacy as a condition of obtaining third party payment prescription drug benefit coverage as defined in rule.
- (2)
  - (a) This section does not prohibit any third party payor of pharmaceutical services, who provides for reimbursement to the pharmacy patient or payment on his behalf, from exercising the right to limit the amount reimbursed for the cost of prescription drugs based upon the cost of identical prescription drugs available through a designated out-of-state pharmacy.
  - (b) Notwithstanding Subsection (2)(a), any third party payor of pharmaceutical services may restrict the type of outlet where a patient may obtain certain prescriptive drugs and devices, such as injectable medications, that are not readily available in all pharmacies. The payor may also restrict access to no more than one mail-order pharmacy.
- (3) Each third party payor of pharmaceutical services shall identify as a part of the third party agreement or contract the designated out-of-state pharmacy which shall be used as the base line comparison.
- (4)
  - (a) A violation of this section is a class A misdemeanor.
  - (b) Each violation of this section is a separate offense.

Enacted by Chapter 280, 2004 General Session

**58-17b-620 Prescriptions issued within the public health system.**

- (1) As used in this section:
  - (a) "Department of Health" means the state Department of Health created in Section 26-1-4.
  - (b) "Health department" means either the Department of Health or a local health department.
  - (c) "Local health departments" mean the local health departments created in Title 26A, Chapter 1, Local Health Departments.
- (2) When it is necessary to treat a reportable disease or non-emergency condition that has a direct impact on public health, a health department may implement the prescription procedure described in Subsection (3) for a prescription drug that is not a controlled substance for use in:
  - (a) a clinic; or
  - (b) a remote or temporary off-site location, including a triage facility established in the community, that provides:
    - (i) treatment for sexually transmitted infections;
    - (ii) fluoride treatment;
    - (iii) travel immunization;
    - (iv) preventative treatment for an individual with latent tuberculosis infection;
    - (v) preventative treatment for an individual at risk for an infectious disease that has a direct impact on public health when the treatment is indicated to prevent the spread of disease or to mitigate the seriousness of infection in the exposed individual; or
    - (vi) other treatment as defined by the Department of Health rule.
- (3) In a circumstance described in Subsection (2), an individual with prescriptive authority may write a prescription for each contact, as defined in Section 26-6-2, of a patient of the individual with prescriptive authority without a face-to-face exam, if:
  - (a) the individual with prescriptive authority is treating the patient for a reportable disease or non-emergency condition having a direct impact on public health; and
  - (b) the contact's condition is the same as the patient of the individual with prescriptive authority.

- (4) The following prescription procedure shall be carried out in accordance with the requirements of Subsection (5) and may be used only in the circumstances described under Subsections (2) and (3):
  - (a) a physician writes and signs a prescription for a prescription drug, other than a controlled substance, without the name and address of the patient and without the date the prescription is provided to the patient; and
  - (b) the physician authorizes a registered nurse employed by the health department to complete the prescription written under this Subsection (4) by inserting the patient's name and address, and the date the prescription is provided to the patient, in accordance with the physician's standing written orders and a written health department protocol approved by the physician and the medical director of the state Department of Health.
- (5) A physician assumes responsibility for all prescriptions issued under this section in the physician's name.
- (6)
  - (a) All prescription forms to be used by a physician and health department in accordance with this section shall be serially numbered according to a numbering system assigned to that health department.
  - (b) All prescriptions issued shall contain all information required under this chapter and rules adopted under this chapter.

Amended by Chapter 150, 2012 General Session

**58-17b-621 Automated pharmacy systems.**

Automated pharmacy systems can be utilized in licensed pharmacies, remote locations under the jurisdiction of the Utah State Board of Pharmacy, and licensed health care facilities where legally permissible, as approved by the division in collaboration with the board, and described in rule.

Enacted by Chapter 280, 2004 General Session

**58-17b-622 Pharmacy benefit management services -- Auditing of pharmacy records -- Appeals.**

- (1) For purposes of this section:
  - (a) "Audit" means a review of the records of a pharmacy by or on behalf of an entity that finances or reimburses the cost of health care services or pharmaceutical products.
  - (b) "Entity" includes:
    - (i) a pharmacy benefits manager or coordinator;
    - (ii) a health benefit plan;
    - (iii) a third party administrator as defined in Section 31A-1-301;
    - (iv) a state agency; or
    - (v) a company, group, or agent that represents, or is engaged by, one of the entities described in Subsections (1)(b)(i) through (iv).
  - (c) "Fraud" means an intentional act of deception, misrepresentation, or concealment in order to gain something of value.
  - (d) "Health benefit plan" means:
    - (i) a health benefit plan as defined in Section 31A-1-301; or
    - (ii) a health, dental, medical, Medicare supplement, or conversion program offered under Title 49, Chapter 20, Public Employees' Benefit and Insurance Program Act.

- (2)
  - (a) Except as provided in Subsection (2)(b), this section applies to:
    - (i) a contract for the audit of a pharmacy entered into, amended, or renewed on or after July 1, 2012; and
    - (ii) an entity that conducts an audit of the pharmacy records of a pharmacy licensed under this chapter.
  - (b) This section does not apply to an audit of pharmacy records:
    - (i) for a federally funded prescription drug program, including:
      - (A) the state Medicaid program;
      - (B) the Medicare Part D program;
      - (C) a Department of Defense prescription drug program;
      - (D) a Veterans Affairs prescription drug program; or
    - (ii) when fraud or other intentional and willful misrepresentation is alleged and the pharmacy audit entity has evidence that the pharmacy's actions reasonably indicate fraud or intentional and willful misrepresentation.
- (3)
  - (a) An audit that involves clinical or professional judgment shall be conducted by or in consultation with a pharmacist who is employed by or working with the auditing entity and who is licensed in the state or another state.
  - (b) If an audit is conducted on site at a pharmacy, the entity conducting the audit:
    - (i) shall give the pharmacy 10 days advanced written notice of:
      - (A) the audit; and
      - (B) the range of prescription numbers or a date range included in the audit; and
    - (ii) may not audit a pharmacy during the first five business days of the month, unless the pharmacy agrees to the timing of the audit.
  - (c) An entity may not audit claims:
    - (i) submitted more than 18 months prior to the audit, unless:
      - (A) required by federal law; or
      - (B) the originating prescription is dated in the preceding six months; or
    - (ii) that exceed 200 selected prescription claims.
- (4)
  - (a) An entity may not:
    - (i) include dispensing fees in the calculations of overpayments unless the prescription is considered a misfill;
    - (ii) recoup funds for prescription clerical or recordkeeping errors, including typographical errors, scrivener's errors, and computer errors on a required document or record unless the audit entity is alleging fraud or other intentional or willful misrepresentation and the audit entity has evidence that the pharmacy's actions reasonably indicate fraud or intentional and willful misrepresentation;
    - (iii) recoup funds for refills dispensed in accordance with Section 58-17b-608.1, unless the health benefit plan does not cover the prescription drug dispensed by the pharmacy; or
    - (iv) collect any funds, charge-backs, or penalties until the audit and all appeals are final, unless the audit entity is alleging fraud or other intentional or willful misrepresentation and the audit entity has evidence that the pharmacy's actions reasonably indicate fraud or intentional and willful misrepresentation.
  - (b) Auditors shall only have access to previous audit reports on a particular pharmacy if the previous audit was conducted by the same entity except as required for compliance with state or federal law.

- (5) A pharmacy subject to an audit may use the following records to validate a claim for a prescription, refill, or change in a prescription:
  - (a) electronic or physical copies of records of a health care facility, or a health care provider with prescribing authority; and
  - (b) any prescription that complies with state law.
- (6)
  - (a) An entity that audits a pharmacy shall provide the pharmacy with a preliminary audit report, delivered to the pharmacy or its corporate office of record within 60 days after completion of the audit.
  - (b) A pharmacy has 30 days following receipt of the preliminary audit report to respond to questions, provide additional documentation, and comment on and clarify findings of the audit. Receipt of the report shall be based on the postmark date or the date of a computer transmission if transferred electronically.
- (7) If an audit results in the dispute or denial of a claim, the entity conducting the audit shall allow the pharmacy to resubmit a claim using any commercially reasonable method, including fax, mail, or electronic claims submission provided that the period of time when a claim may be resubmitted has not expired under the rules of the plan sponsor.
- (8)
  - (a) Within 120 days after the completion of the appeals process under Subsection (9), a final audit report shall be delivered to the pharmacy or its corporate office of record.
  - (b) The final audit report shall include a disclosure of any money recovered by the entity that conducted the audit.
- (9) An entity that audits a pharmacy shall establish a written appeals process for appealing a preliminary audit report and a final audit report, and shall provide the pharmacy with notice of the written appeals process. If the pharmacy benefit manager's contract or provider manual contains the information required by this Subsection (9), the requirement for notice is met.

Amended by Chapter 39, 2018 General Session

**58-17b-623 Disposal of unused prescription drugs.**

- (1) A pharmacy may accept unused prescription drugs for disposal in accordance with administrative rules adopted by the division.
- (2) The division shall adopt administrative rules regarding a pharmacy accepting unused prescription drugs for disposal as permitted by federal law and regulation relating to the disposal of unused prescription drugs.

Enacted by Chapter 61, 2012 General Session

**58-17b-624 Prescription drugs -- Sale to a practitioner for office use.**

- (1) A pharmacy licensed under this chapter may, subject to rules established by the division, repackage or compound a prescription drug for sale to a practitioner if:
  - (a) the prescription drug:
    - (i) does not include a compounded drug; or
    - (ii)
      - (A) includes a compounded drug; and
      - (B) is not a controlled substance;
  - (b) the pharmacy labels the prescription drug "for office use only";
  - (c) the practitioner administers the drug to a patient in the practitioner's office or facility; and

- (d) except in accordance with Title 58, Chapter 17b, Part 8, Dispensing Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy, the practitioner does not dispense the drug to the patient.
- (2) The division shall establish, in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, prescription drug labeling and control standards for a prescription drug that a pharmacy provides to a practitioner under this section.

Enacted by Chapter 385, 2014 General Session

Amended by Chapter 385, 2014 General Session, (Coordination Clause)

**58-17b-625 Administration of a long-acting injectable drug therapy.**

- (1) A pharmacist may, in accordance with this section, administer a drug described in Subsection (2).
- (2) Notwithstanding the provisions of Subsection 58-17b-102(57)(c)(ii)(B), the division shall make rules, in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, establishing training for a pharmacist to administer the following long-acting injectables intramuscularly:
  - (a) aripiprazole;
  - (b) paliperidone;
  - (c) risperidone;
  - (d) olanzapine;
  - (e) naltrexone;
  - (f) naloxone; and
  - (g) drugs approved and regulated by the United States Food and Drug Administration for the treatment of the Human Immunodeficiency Virus.
- (3) A pharmacist may not administer a drug listed under Subsection (2) unless the pharmacist:
  - (a) completes the training described in Subsection (2);
  - (b) administers the drug at a clinic or community pharmacy, as those terms are defined by the division, by administrative rule made in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act; and
  - (c) is directed by the physician, as that term is defined in Section 58-67-102 or Section 58-68-102, who issues the prescription to administer the drug.

Enacted by Chapter 384, 2017 General Session

**58-17b-626 Direct or indirect remuneration by pharmacy benefits managers -- Disclosure of customer costs.**

- (1) As used in this section:
  - (a) "Cost share" means the amount paid by an insured customer under the customer's health benefit plan.
  - (b) "Direct or indirect remuneration" means any adjustment in the total compensation:
    - (i) received by a pharmacy from a pharmacy benefits manager or coordinator for the sale of a drug, device, or other product or service; and
    - (ii) that is determined after the sale of the product or service.
  - (c) "Health benefit plan" means the same as that term is defined in Section 31A-1-301.
  - (d) "Pharmacy services administration organization" means an entity that contracts with a pharmacy to assist with third-party payer interactions and administrative services related to third-party payer interactions, including:



- (i) contracting with a pharmacy benefits manager or coordinator on behalf of the pharmacy; and
  - (ii) managing a pharmacy's claims payments from third-party payers.
- (e) "Pharmacy service entity" means:
- (i) a pharmacy services administration organization; or
  - (ii) a pharmacy benefits manager or coordinator.
- (f)
- (i) "Reimbursement report" means a report on the adjustment in total compensation for a claim.
  - (ii) "Reimbursement report" does not include a report on adjustments made pursuant to a pharmacy audit or reprocessing.
- (g) "Sale" means a prescription drug claim covered by a health benefit plan.
- (2) If a pharmacy service entity engages in direct or indirect remuneration with a pharmacy, the pharmacy service entity shall make a reimbursement report available to the pharmacy upon the pharmacy's request.
- (3) For the reimbursement report described in Subsection (2), the pharmacy service entity shall:
- (a) include the adjusted compensation amount related to a claim and the reason for the adjusted compensation; and
  - (b) provide the reimbursement report:
    - (i) in accordance with the contract between the pharmacy and the pharmacy service entity;
    - (ii) in an electronic format that is easily accessible; and
    - (iii) within 120 days after the day on which the pharmacy benefits manager or coordinator receives a report of a sale of a product or service by the pharmacy.
- (4) A pharmacy service entity shall, upon a pharmacy's request, provide the pharmacy with:
- (a) the reasons for any adjustments contained in a reimbursement report; and
  - (b) an explanation of the reasons provided in Subsection (4)(a).
- (5)
- (a) A pharmacy benefits manager or coordinator may not prohibit or penalize the disclosure by a pharmacist of:
    - (i) an insured customer's cost share for a covered prescription drug;
    - (ii) the availability of any therapeutically equivalent alternative medications; or
    - (iii) alternative methods of paying for the prescription medication, including paying the cash price, that are less expensive than the cost share of the prescription drug.
  - (b) Penalties that are prohibited under Subsection (5)(a) include increased utilization review, reduced payments, and other financial disincentives.
- (6) A pharmacy benefits manager or coordinator may not require an insured customer to pay, for a covered prescription drug, more than the lesser of:
- (a) the applicable cost share of the prescription drug being dispensed; or
  - (b) the retail price of the drug without prescription drug coverage.

Enacted by Chapter 305, 2018 General Session

## **Part 7 Incapacity**

### **58-17b-701 Mentally incompetent or incapacitated pharmacist -- Division action and procedures.**

- (1) As used in this section:

- (a) "Incapacitated person" is a person who is incapacitated, as defined in Section 75-1-201.
  - (b) "Mental illness" is as defined in Section 62A-15-602.
- (2) If a court of competent jurisdiction determines a pharmacist is an incapacitated person, or that the pharmacist has a mental illness and is unable to safely engage in the practice of pharmacy, the director shall immediately suspend the license of the pharmacist upon the entry of the judgment of the court, without further proceedings under Title 63G, Chapter 4, Administrative Procedures Act, regardless of whether an appeal from the court's ruling is pending. The director shall promptly notify the pharmacist, in writing, of the suspension.
- (3)
- (a) If the division and a majority of the board find reasonable cause to believe a pharmacist, who is not determined judicially to be an incapacitated person or to have a mental illness, is incapable of practicing pharmacy with reasonable skill regarding the safety of patients, because of illness, excessive use of drugs or alcohol, or as a result of any mental or physical condition, the board shall recommend that the director file a petition with the division, and cause the petition to be served upon the pharmacist with a notice of hearing on the sole issue of the capacity of the pharmacist to competently and safely engage in the practice of pharmacy.
  - (b) The hearing shall be conducted under Section 58-1-109 and Title 63G, Chapter 4, Administrative Procedures Act, except as provided in Subsection (4).
- (4)
- (a) Every pharmacist who accepts the privilege of being licensed under this chapter gives consent to:
    - (i) submitting at the pharmacist's own expense to an immediate mental or physical examination when directed in writing by the division, with the consent of a majority of the board, to do so; and
    - (ii) the admissibility of the reports of the examining practitioner's testimony or examination in any proceeding regarding the license of the pharmacist, and waives all objections on the ground the reports constitute a privileged communication.
  - (b) The examination may be ordered by the division, with the consent of a majority of the board, only upon a finding of reasonable cause to believe:
    - (i) the pharmacist has a mental illness, is incapacitated or otherwise unable to practice pharmacy with reasonable skill and safety; and
    - (ii) immediate action by the division and the board is necessary to prevent harm to the pharmacist's patients or the general public.
  - (c)
    - (i) Failure of a pharmacist to submit to the examination ordered under this section is a ground for the division's immediate suspension of the pharmacist's license by written order of the director.
    - (ii) The division may enter the order of suspension without further compliance with Title 63G, Chapter 4, Administrative Procedures Act, unless the division finds the failure to submit to the examination ordered under this section was due to circumstances beyond the control of the pharmacist and was not related directly to the illness or incapacity of the pharmacist.
- (5)
- (a) A pharmacist whose license is suspended under Subsection (2) or (4) has the right to a hearing to appeal the suspension within 10 days after the license is suspended.
  - (b) The hearing held under this Subsection (5) shall be conducted in accordance with Sections 58-1-108 and 58-1-109 for the sole purpose of determining if sufficient basis exists for the

continuance of the order of suspension in order to prevent harm to the pharmacist's patients or the general public.

- (6) A pharmacist whose license is revoked, suspended, or in any way restricted under this section may request the division and the board to consider, at reasonable intervals, evidence presented by the pharmacist, under procedures established by division rule, regarding any change in the pharmacist's condition, to determine whether:
- (a) the pharmacist is or is not able to safely and competently engage in the practice of pharmacy; and
  - (b) the pharmacist is qualified to have the pharmacist's licensure to practice under this chapter restored completely or in part.

Amended by Chapter 364, 2013 General Session

## **Part 8**

### **Dispensing Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy**

#### **58-17b-801 Title.**

This part is known as "Dispensing Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy."

Enacted by Chapter 72, 2014 General Session

#### **58-17b-802 Definitions.**

As used in this part:

- (1)
- (a) "Cosmetic drug" means 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" 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 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)
  - (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.
- (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.

Amended by Chapter 159, 2016 General Session

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

- (1) An applicant for a license 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 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, 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 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 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.

Amended by Chapter 206, 2015 General Session

**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) Notwithstanding Section 58-17b-302, 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 by the division in consultation with the Board of Pharmacy and the 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 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.

Enacted by Chapter 72, 2014 General Session

**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 as a dispensing medical practitioner with a scope of practice that permits the dispensing medical practitioner to 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); and
  - (b) is certified or eligible to be certified by the American Board of Internal Medicine in medical oncology.
- (3) A dispensing medical practitioner authorized to prescribe and dispense a cancer drug treatment regimen under this section may prescribe and dispense a cancer drug treatment regimen:
  - (a) to the practitioner's patient who is currently undergoing chemotherapy in an outpatient clinic setting; and
  - (b) if the 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.

Enacted by Chapter 72, 2014 General Session

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

- (1)
  - (a) 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 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 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 Section 58-17b-804.

Enacted by Chapter 72, 2014 General Session

**Part 9**  
**Charitable Prescription Drug Recycling Act**

**58-17b-901 Title.**

This part is known as the "Charitable Prescription Drug Recycling Act."

Enacted by Chapter 405, 2016 General Session

**58-17b-902 Definitions.**

As used in this part:

- (1) "Assisted living facility" means the same as that term is defined in Section 26-21-2.

- (2) "Cancer drug" means a drug that controls or kills neoplastic cells and includes a drug used in chemotherapy to destroy cancer cells.
- (3) "Charitable clinic" means a charitable nonprofit corporation that:
  - (a) holds a valid exemption from federal income taxation issued under Section 501(a), Internal Revenue Code;
  - (b) is exempt from federal income taxation under Section 501(c)(3), Internal Revenue Code;
  - (c) provides, on an outpatient basis, for a period of less than 24 consecutive hours, to an individual not residing or confined at a facility owned or operated by the charitable nonprofit corporation:
    - (i) advice;
    - (ii) counseling;
    - (iii) diagnosis;
    - (iv) treatment;
    - (v) surgery; or
    - (vi) care or services relating to the preservation or maintenance of health; and
  - (d) has a licensed outpatient pharmacy.
- (4) "Charitable pharmacy" means an eligible pharmacy that is operated by a charitable clinic.
- (5) "County health department" means the same as that term is defined in Section 26A-1-102.
- (6) "Donated prescription drug" means a prescription drug that an eligible donor donates to an eligible pharmacy under the program.
- (7) "Eligible donor" means a donor that donates a prescription drug from within the state and is:
  - (a) a nursing care facility;
  - (b) an assisted living facility;
  - (c) a licensed intermediate care facility for people with an intellectual disability;
  - (d) a manufacturer;
  - (e) a pharmaceutical wholesale distributor;
  - (f) an eligible pharmacy; or
  - (g) a physician's office.
- (8) "Eligible pharmacy" means a pharmacy that:
  - (a) is registered by the division as eligible to participate in the program; and
  - (b) is operated by:
    - (i) a county;
    - (ii) a county health department;
    - (iii) a pharmacy under contract with a county health department;
    - (iv) the Department of Health, created in Section 26-1-4;
    - (v) the Division of Substance Abuse and Mental Health, created in Section 62A-15-103; or
    - (vi) a charitable clinic.
- (9) "Eligible prescription drug" means a prescription drug, described in Section 58-17b-904, that is not:
  - (a) a controlled substance; or
  - (b) a drug that can only be dispensed to a patient registered with the drug's manufacturer in accordance with federal Food and Drug Administration requirements.
- (10) "Licensed intermediate care facility for people with an intellectual disability" means the same as that term is defined in Section 58-17b-503.
- (11) "Medically indigent individual" means an individual who:
  - (a)
    - (i) does not have health insurance; and
    - (ii) lacks reasonable means to purchase prescribed medications; or

- (b)
  - (i) is covered under Medicaid or Medicare; and
  - (ii) lacks reasonable means to pay the insured's portion of the cost of the prescribed medications.
- (12) "Nursing care facility" means the same as that term is defined in Section 26-18-501.
- (13) "Physician's office" means a fixed medical facility that:
  - (a) is staffed by a physician, physician's assistant, nurse practitioner, or registered nurse, licensed under Title 58, Occupations and Professions; and
  - (b) treats an individual who presents at, or is transported to, the facility.
- (14) "Program" means the Charitable Prescription Drug Recycling Program created in Section 58-17b-903.
- (15) "Unit pack" means the same as that term is defined in Section 58-17b-503.
- (16) "Unlawful conduct" means the same as that term is defined in Sections 58-1-501 and 58-17b-501.
- (17) "Unprofessional conduct" means the same as that term is defined in Sections 58-1-501 and 58-17b-502.

Enacted by Chapter 405, 2016 General Session

**58-17b-903 Charitable Prescription Drug Recycling Program -- Creation -- Requirements.**

- (1) There is created the Charitable Prescription Drug Recycling Program.
- (2) The division, in consultation with the board, shall:
  - (a) implement the program, on a statewide basis, to permit an eligible donor to transfer an eligible prescription drug to an eligible pharmacy for dispensing to a medically indigent individual;
  - (b) in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, make rules necessary to implement the program; and
  - (c) provide technical assistance to entities that desire to participate in the program.

Enacted by Chapter 405, 2016 General Session

**58-17b-904 Criteria for eligible prescription drugs.**

An eligible pharmacy may not accept or dispense an unused prescription drug under the program unless the unused prescription drug:

- (1)
  - (a) is in a unit pack or the manufacturer's sealed container; or
  - (b) is an injectable medication;
- (2)
  - (a) is unopened; or
  - (b) is a cancer drug packaged in an unopened single-unit dose that has been removed from a multi-dose package;
- (3) is accepted and dispensed by the eligible pharmacy before:
  - (a) a beyond use date that appears on the label;
  - (b) the expiration date recommended by the manufacturer; or
  - (c) a date, established by division rule for a specific prescription drug, in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, that is later than the date in Subsection (3)(a) or (3)(b);
- (4)
  - (a) is not adulterated or mislabeled; and



- (b) the pharmacist or licensed pharmacist technician accepting or dispensing the prescription drug does not have reason to believe that the prescription drug is adulterated or mislabeled.

Enacted by Chapter 405, 2016 General Session

**58-17b-905 Participation in program -- Requirements -- Fees.**

- (1) An eligible donor or an eligible pharmacy may participate in the program.
- (2) An eligible pharmacy:
  - (a) shall comply with all applicable federal and state laws related to the storage and distribution of a prescription drug;
  - (b) shall comply with all applicable federal and state laws related to the acceptance and transfer of a prescription drug, including 21 U.S.C. Chapter 9, Subchapter V, Part H, Pharmaceutical Distribution Supply Chain;
  - (c) shall, before accepting or dispensing a prescription drug under the program, inspect each prescription drug to determine whether the prescription drug is an eligible prescription drug;
  - (d) may dispense an eligible prescription drug to a medically indigent individual who:
    - (i) is a resident of the state; and
    - (ii) has a prescription issued by a practitioner;
  - (e) may charge a handling fee, adopted by the division under Section 63J-1-504; and
  - (f) may not accept, transfer, or dispense a prescription drug in violation of the federal Food, Drug, and Cosmetic Act, 21 U.S.C. Sec. 301 et seq.

Enacted by Chapter 405, 2016 General Session

**58-17b-906 Liability of participating organizations and manufacturers.**

In the absence of bad faith or gross negligence, a person is not criminally or civilly liable for injury, death, or loss of property based solely on the fact that the person manufactured, provided, donated, accepted, or dispensed an eligible prescription drug under this part.

Enacted by Chapter 405, 2016 General Session

**58-17b-907 Rules made by the division.**

The rules made by the division under Subsection 58-17b-903(2)(b) shall include:

- (1) registration requirements to establish the eligibility of a pharmacy to participate in the program;
- (2) a formulary that includes all eligible prescription drugs approved by the federal Food and Drug Administration;
- (3) standards and procedures for:
  - (a) verifying whether a pharmacy or pharmacist participating in the program is licensed and in good standing with the board;
  - (b) handling of a donated eligible prescription drug, including:
    - (i) acceptance;
    - (ii) identification, including redundant criteria for verification;
    - (iii) documentation, under 21 U.S.C. Sec. 360eee-1, of transaction information, history, and statements;
    - (iv) safe storage;
    - (v) security;
    - (vi) inspection;
    - (vii) transfer; and

- (viii) dispensing;
- (c) a pharmacist or licensed pharmacy technician working in or consulting with a participating eligible donor;
- (d) disposition of a donated prescription drug that is a controlled substance;
- (e) record keeping regarding:
  - (i) the eligible donor that donated each prescription drug;
  - (ii) the identification and evaluation of a donated prescription drug by a pharmacist or licensed pharmacy technician; and
  - (iii) the dispensing or disposition of a prescription drug;
- (f) determining the status of a medically indigent individual;
- (g) labeling requirements to:
  - (i) ensure compliance with patient privacy laws relating to:
    - (A) an individual who receives an eligible prescription drug; and
    - (B) patient information that may appear on a donated prescription drug;
  - (ii) clearly identify an eligible prescription drug dispensed under the program; and
  - (iii) communicate necessary information regarding the manufacturer's recommended expiration date or the beyond use date; and
- (h) ensuring compliance with the requirements of this part;
- (4) a process for seeking input from:
  - (a) the Department of Health, created in Section 26-1-4, to establish program standards and procedures for assisted living facilities and nursing care facilities; and
  - (b) the Division of Substance Abuse and Mental Health, created in Section 62A-15-103, to establish program standards and procedures for mental health and substance abuse clients; and
- (5) the creation of a special training program that a pharmacist and a licensed pharmacy technician at an eligible pharmacy must complete before participating in the program.

Enacted by Chapter 405, 2016 General Session