

PHARMACY PRACTICE ACT

Part 1. General Provisions

58-17b-101. Title.

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

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.S. 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) "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.
- (8) "Board of pharmacy" or "board" means the Utah State Board of

- Pharmacy created in Section 58-17b-201.
- (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 located in Utah that is authorized to engage in the manufacture, production, wholesale, or distribution of drugs or devices.
 - (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" has the same definition as in Section 58-37-2.
- (21) "Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component part or accessory, which is required under federal or state law to be prescribed by a practitioner and dispensed by a pharmacist or pharmacy intern.
- (22) "Dietary supplement" has the same meaning as Public Law Title 103, Chapter 417, Sec. 3a(ff) which is incorporated by reference.
- (23) "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.
- (24) "Distribute" means to deliver a drug or device other than by administering or dispensing.
- (25) "Drug" means:
 - (a) a substance recognized as a drug in any official compendium, or supplement thereto, designated from time to time by the division in collaboration with the board for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals, excluding nonprescription drugs or dietary supplements;
 - (b) a drug or device that is required by any applicable federal or state law or rule to be dispensed on prescription only or is restricted to use by practitioners only;
 - (c) substances other than food intended to affect the structure or any function of the body of humans or other animals, excluding nonprescription dietary supplements; and
 - (d) substances intended for use as a component of any substance specified in Subsection (25)(a), (b), or (c).
- (26) "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 Federal Food and Drug Administration.

- (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) "Extern" means a college of pharmacy student enrolled in a college coordinated practical experience program in a health care setting under the supervision of a preceptor, as defined in this act, and approved by a college of pharmacy.
- (32) "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.
- (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.S. Sec. 352 (2003).
 - (39) "Nonprescription drug" means a drug which may be sold without a prescription and which is labeled for use by the consumer in accordance with federal law and 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 any prescription drug or device to other than the consumer or user of the prescription drug or device, which 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 offer to sell, purchase or trade a prescription drug or device between hospitals or other health care facilities that are under common ownership or control of the management and operation of the facilities;
 - (iii) the sale, purchase, or trade of a prescription drug or device, or offer to sell, purchase, or trade a prescription drug or device for emergency medical reasons, or to supply another pharmaceutical facility to alleviate a temporary shortage; or
 - (iv) the distribution of a prescription drug or device as a sample by representatives of a manufacturer.
- (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 two 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 administers the prescription drug or device portion of a health insurance plan 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 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 and prescribed drug prepared for dispensing, dispensing of the drug, or counseling a patient with respect to a prescription drug;
 - (ii) counseling regarding nonprescription drugs and dietary supplements unless delegated by the supervising pharmacist; or
 - (iii) 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.
- (56) "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 Physician's 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; and
- (m) formulary management intervention.
- (57) "Practice of telepharmacy" means the practice of pharmacy through the use of telecommunications and information technologies.
- (58) "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.
- (59) "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.
- (60) "Prescription" means an order:
 - (a) issued by a licensed practitioner:
 - (i) orally, in writing, by telephone, facsimile transmission, computer, or other electronic means of communication as defined by division rule;
 - (ii) in the course of the practitioner's professional practice; or
 - (iii) by collaborative pharmacy practice agreement; and
 - (b) for a controlled substance, other prescription drug, or device with the intent that the controlled substance, prescription drug, or device will be used by a patient or an animal.
- (61) "Prescription drug or device" means:
 - (a) a legend drug or device; or
 - (b) a drug or device that is required by an applicable federal

- or state law or rule to be dispensed on prescription only or is restricted to use by practitioners only.
- (62) "Retail pharmacy" means a pharmaceutical facility dispensing prescription drugs and devices to the general public.
 - (63) "Self-audit" means an internal evaluation of a pharmacy to determine compliance with this chapter.
 - (64) "Supervising pharmacist" means a pharmacist who is overseeing the operation of the pharmacy during a given day or shift.
 - (65) "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.
 - (66) "Unlawful conduct" is as defined in Sections 58-1-501 and 58-17b-501.
 - (67) "Unprofessional conduct" is as defined in Sections 58-1-501 and 58-17b-502 and may be further defined by rule.
 - (68) "Veterinary pharmaceutical facility" means a pharmaceutical facility that dispenses drugs intended for use by animals or for sale to veterinarians for the administration for animals.

58-17b-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) take a drug or device for further analysis if considered necessary;
 - (c) temporarily seize a drug or device which is suspected to be

- adulterated, misbranded, outdated, or otherwise in violation of this chapter, pending an adjudicative proceeding on the matter;
- (d) box and seal drugs suspected to be adulterated, outdated, misbranded, or otherwise in violation of this chapter; and
 - (e) dispose of or return any drug or device obtained under this Subsection (3) in accordance with procedures established by division rule.
- (4) An inspection conducted under Subsection (1) shall be 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 Control Substances Act, or any 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.

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 58-37-7.5 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.

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, or the practice of a pharmacy technician, 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; or
 - (c) pharmacy technician.

58-17b-302. License classifications of 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; or
 - (e) class E 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.

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

- (1) Each 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 required by Section 58-17b-307, or 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) Each 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) Each 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 required by Section 58-17b-307, or as otherwise 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.

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

Each 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 required by Section 58-17b-307, or as otherwise 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;
 - (b) have graduated and received a pharmacy degree from a school or college of pharmacy which is accredited by the Accreditation Council on Pharmacy Education but not completed the internship hours required by division rule for licensure as a pharmacist; or
 - (c) 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.

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

- (1) Each 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 required by Section 58-17b-307, or as otherwise permitted by 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

- (f) safety to the public;
 - (f) have completed a board approved 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 shall not be eligible to be a licensed pharmacy technician while on probation with the division.

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

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

- (1) An applicant for licensure under this chapter shall submit fingerprint cards in a form acceptable to the division at the time the license application is filed and shall consent to a fingerprint background check by the Utah Bureau of Criminal Identification and the Federal Bureau of Investigation regarding the application.
- (2) The division shall request the Department of Public Safety to complete a Federal Bureau of Investigation criminal background check for each applicant through the National Criminal History System (NCIC) or any successor system.
- (3) If convicted of one or more felonies, an applicant must receive an absolute discharge from the sentences for all felony convictions five or more years prior to the date of filing an application for licensure under this chapter.
- (4) For purposes of conducting the criminal background check required in Subsection (1), the division shall have direct access to criminal background information maintained pursuant to Title 53, Chapter 10, Part 2, Bureau of Criminal Identification.
- (5) Any new pharmacist, pharmacy intern, or pharmacy technician license issued under this section shall be conditional, pending completion of the criminal background check. Notwithstanding Title 63G, Chapter 4, Administrative Procedures Act, if the criminal background check discloses the applicant has failed to accurately disclose a criminal history, the license shall be immediately and automatically revoked upon notice to the licensee.
- (6) Any person whose conditional license has been revoked under Subsection (5) shall be entitled to a postrevocation hearing to challenge the revocation. The hearing shall be conducted in accordance with Title 63G, Chapter 4, Administrative Procedures Act.

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 (c); 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.

58-17b-309. Exemptions from licensure.

- (1) 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 Subsection (1) without being licensed under this chapter:
 - (a) a person selling or providing contact lenses in accordance with Section 58-16a-801; and
 - (b) an individual engaging in the practice of pharmacy technician under the direct personal supervision of a pharmacist while making satisfactory progress in an approved program as defined in division rule.
- (2) In accordance with Subsection 58-1-303(1)(a), an individual exempt under Subsection (1)(b) must take all examinations as required by division rule following completion of an approved curriculum of education, within the required time frame. This exemption expires immediately upon notification of a failing score of an examination, and the individual may not continue working as a pharmacy technician even under direct supervision.

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.

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.

Part 5. Unlawful and Unprofessional Conduct

58-17b-501. Unlawful conduct.

"Unlawful conduct" includes:

- (1) knowingly preventing or refusing to permit any 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 any 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 which contains, as part of that name, the words "drugstore", "pharmacy", "drugs", "medicine store", "medicines", "drug shop", "apothecary", "prescriptions", or any other 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 any 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, any drug or device which 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 his own advantages or revealing to anyone other than the division, board, and its authorized representatives, or to the courts, when relevant to any judicial or administrative proceeding under this chapter, any information acquired under authority of this chapter or concerning any method of process which is a trade secret;
 - (6) procuring or attempting to procure any drug for himself or to have someone else procure or attempt to procure any drug:
 - (a) by fraud, deceit, misrepresentation, or subterfuge;
 - (b) by forgery or alteration of a prescription or any written order;
 - (c) by concealment of a material fact;
 - (d) by use of a false statement in any prescription, chart, order, or report; or
 - (e) by theft;
 - (7) filling, refilling, or advertising the filling or refilling of prescriptions for any 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 any employed pharmacist, pharmacy intern, pharmacy technician, or authorized supportive personnel to engage in any conduct in violation of this chapter;
 - (9) being in possession of a prescription drug for any unlawful purpose;

- (10) dispensing a prescription drug to anyone who does not have a prescription from a practitioner or to anyone who he knows or should know is attempting to obtain drugs by fraud or misrepresentation;
- (11) selling, dispensing, or otherwise trafficking in prescription drugs when not licensed to do so or when not exempted from licensure; and
- (12) using a prescription drug or controlled substance for himself that was not lawfully prescribed for him by a practitioner.

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, accepting back and redistributing of 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 Federal Title II, P.L. 91, Controlled Substances Act, or Title 58, Chapter 37, Utah Controlled Substances Act, or 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 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, preparing a prescription drug for sale to another pharmacist or pharmaceutical facility; and
- (14) as a pharmacist or pharmacy intern, preparing a prescription drug in a dosage form which is regularly and commonly available from a manufacturer in quantities and strengths prescribed by a practitioner.

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

- (1) For purposes of this section:
 - (a) "ICFMR" means an intermediate care facility for the mentally retarded 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" has the same definition as 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) Notwithstanding the provisions of Subsection 58-17b-502(5), a pharmacist may accept back and redistribute any unused drug, or a part of it, after it has left the premises of the pharmacy if:
 - (a) the drug was prescribed to a patient in a nursing care facility, an ICFMR, or state prison facility, county jail, or state hospital;
 - (b) the drug was stored under the supervision of a licensed health care provider according to manufacturer recommendations;
 - (c) the drug is in a unit pack or in the manufacturer's sealed container;
 - (d) the drug was returned to the original dispensing pharmacy;
 - (e) the drug was initially dispensed by a licensed pharmacist or licensed pharmacy intern; and
 - (f) accepting back and redistribution of the drug complies with Federal Food and Drug Administration and Drug Enforcement

Administration regulations.

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 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 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.

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.

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.

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.

58-17b-602. Prescription orders -- Information required -- Alteration -- Labels --Signatures.

- (1) Except as provided in Section 58-1-501.3, the minimum information that shall be included in a prescription order and 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) Each drug dispensed shall have a label securely affixed to the container indicating the following minimum information:
 - (a) the name, address, and telephone number of the pharmacy;
 - (b) the serial number of the prescription as assigned by the dispensing pharmacy;
 - (c) the filling date of the prescription or its last dispensing date;
 - (d) the name of the patient, or in the case of an animal, name of the owner and species of the animal;
 - (e) the name of the prescriber;

- (f) the directions for use and cautionary statements, if any, which are contained in the prescription order or are needed;
 - (g) except as provided in Subsection (6), 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
 - (h) the beyond use date.
- (6) 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.
- (7) Except when it is delivered to the ultimate user via the United States Postal Service, licensed common carrier, or supportive personnel, a prescription drug may be dispensed to the ultimate user or his agent only at a licensed pharmacy.

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.

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.

58-17b-605. Drug product equivalents.

- (1) A pharmacist or pharmacy intern dispensing a prescription order for a specific drug by brand or proprietary name may substitute a drug product equivalent, as defined in Section 58-17b-102, 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 (5); and
 - (f) the substitution is not otherwise prohibited by law.
- (2)
 - (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.
- (3) 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.
- (4) 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.

- (5) (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.
- (6) 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.
- (7) (a) For purposes of Subsection (7), "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 (5)(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 (5)(a) or (b).
- (c) Except as provided in Subsection (7)(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 (7)(c) is not required if the drug product equivalent is paid for in whole or in part by Medicaid.
- (8) Failure of a licensed medical practitioner to specify that no substitution is authorized does not constitute evidence of negligence.

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" means any drug that requires a prescription under state or federal law.
- (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.

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.

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.

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

- (1) Except as provided in Subsection 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.

58-17b-610. Patients' immediate needs.

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 their patients. Immediate need for a patient includes giving out drug samples for up to a three-day supply or the amount necessary to determine the best pharmaceutical agent for that specific patient.

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.

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(64), 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.

58-17b-613. Patient counseling.

- (1) Every pharmacy facility shall orally offer to counsel a patient or a patient's agent in a personal face-to-face discussion with respect to 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 shall provide counseling to each patient, and shall provide the patient with a toll-free telephone number by which the patient may contact a pharmacist at the dispensing pharmacy during normal business hours and receive oral counseling, with respect to each prescription drug dispensed if the patient provides or the prescription is otherwise provided to the pharmacy facility by a means other than personal delivery, and the dispensed prescription drug is mailed or otherwise delivered to the patient outside of the pharmacy facility.
- (3)
 - (a) The provisions of Subsections (1) and (2) do not apply to incarcerated patients or persons otherwise under the jurisdiction of the Utah Department of Corrections or a county detention facility.
 - (b) A written communication with a person described in Subsection (3)(a) shall be used by a pharmacist or pharmacy intern in lieu of a face to face or telephonic communication for the purpose of counseling the patient.

58-17b-614. Notification.

- (1) A pharmacy shall report in writing to the division not later than ten 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.

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.

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.

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.

58-17b-618. Compliance with 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.

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.

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) A health department may implement the prescription procedure under Subsection (3) for prescription drugs, other than controlled substances, for use in clinics providing:
 - (a) sexually transmitted disease treatment;
 - (b) fluoride treatment; or
 - (c) travel immunization.
- (3) The following prescription procedure shall be carried out in accordance with the requirements of Subsection (4) and may be used only in the clinics listed under Subsection (2):
 - (a) a physician writes and signs a prescription for prescription drugs, other than controlled substances, 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 (3) 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.
- (4) When allowing prescriptions to be written under Subsection (3), the health department shall employ a physician who:
 - (a) assumes specific responsibility for all prescriptions issued in his name under the procedure in Subsection (3) by the health department; and
 - (b) enters into a written, signed agreement with the health department, which agreement is approved by the division and state:
 - (i) the terms and conditions under which the physician will prepare and sign prescriptions that do not include the name and address of the patient and the date the prescription is provided to the patient;
 - (ii) the methods which will be used to ensure the signed prescriptions are secure and not available for unauthorized use;
 - (iii) the minimum qualifications and training of a registered nurse authorized by the physician and department to complete and provide prescriptions to a patient;
 - (iv) under what conditions prescriptions completed by an

- authorized registered nurse will be provided to a patient in accordance with standing orders and written protocols, and the specific prescription drugs for which prescriptions may be written;
- (v) the manner in which the physician will audit and review the records of patients receiving prescriptions; and
 - (vi) the manner in which records of prescriptions issued will be maintained for audit by the physician and division.
- (5) The health department shall file and maintain with the division a current copy of all agreements signed by physicians under Subsection (4).
- (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.

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.

Part 7. Incapacity

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

- (1) As used in this section:
- (a) "Incapacitated person" has the same definition as in Section 75-1-201.
 - (b) "Mentally ill" has the same definition as in Section 62A-15-602.
- (2) If a court of competent jurisdiction determines a pharmacist is an incapacitated person, or that the pharmacist is mentally ill and 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 be mentally ill, 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 is mentally ill or 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 ten 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.

PHARMACY PRACTICE ACT

**Title 58, Chapter 17b
Utah Code Annotated 1953
As Amended by
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