

R156. Commerce, Occupational and Professional Licensing.

R156-17b. Pharmacy Practice Act Rule.

R156-17b-101. Title.

This rule is known as the "Pharmacy Practice Act Rule".

R156-17b-102. Definitions.

In addition to the definitions in Title 58, Chapter 1, Division of Occupational and Professional Licensing Act, and Title 58, Chapter 17b, Pharmacy Practice Act, the following rule definitions supplement the statutory definitions:

- (1) "Accredited by ASHP" means a program that:
 - (a) was accredited by the ASHP on the day the applicant for licensure completed the program; or
 - (b) was in ASHP candidate status on the day the applicant for licensure completed the program.
- (2) "ACPE" means the American Council on Pharmaceutical Education or Accreditation Council for Pharmacy Education.
- (3) "Analytical laboratory":
 - (a) means a facility in possession of prescription drugs for analysis; and
 - (b) 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 pre-diluted 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) "Area of need" as used in Subsection 58-17b-612(1)(b)(i) means:
 - (a) a remote-rural hospital, as defined in Section 26-21-13.6;
 - (b) a county of the fourth, fifth, or sixth class, as classified in Section 17-50-501; or
 - (c) any area where a demonstration of need is approved by the Division in collaboration with the Board, based on any factors affecting the access of persons in that area to pharmacy resources.
- (5) "ASHP" means the American Society of Health System Pharmacists.
- (6) "Authorized distributor of record" means a pharmaceutical wholesaler with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drugs. An ongoing relationship is deemed to exist, as defined in Section 1504 of the Internal Revenue Code, if the pharmaceutical wholesaler:
 - (a) has a written agreement currently in effect with the manufacturer evidencing the ongoing relationship; and
 - (b) is listed on the manufacturer's current list of authorized distributors of record.
- (7) "Authorized personnel" means any person who is a part of the pharmacy staff who participates in the pharmacy's operational processes of the pharmacy and contributes to the natural flow of pharmaceutical care.
- (8) "Chain pharmacy warehouse" means a physical location for prescription drugs that acts as a central warehouse and performs intracompany sales or transfers of the prescription drugs to a group of chain pharmacies with the same common ownership and control.
- (9) "Clinic" as used in Subsection 58-17b-625(3)(b) means a Class B pharmacy as defined in Subsection 58-17b-102(11), or a facility that provides outpatient health care services whose primary practice includes the therapeutic use of drugs related to a specific patient for:
 - (a) curing or preventing the patient's disease;
 - (b) eliminating or reducing the patient's disease; or
 - (c) arresting or slowing a disease process.
- (10) "Co-licensed partner" means a person that has the right to engage in the manufacturing or marketing of a co-licensed product.
- (11) "Co-licensed product" means a device or prescription drug for which two or more persons have the right to engage in the manufacturing, marketing, or both consistent with 21 CFR 203 (2021).
- (12) "Community pharmacy" as used in Subsection 58-17b-625(3)(b) means a Class A pharmacy as defined in Subsection 58-17b-102(10).
- (13) "Compounding," as defined in Subsection 58-17b-102(18), in accordance with 21 U.S.C. 353a(e) Pharmacy Compounding, does not include:
 - (a) mixing, reconstituting, or other such acts that are performed in accordance with directions in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling; or
 - (b) the addition of flavoring agents to conventionally manufactured and commercially prepared available liquid medications, if the flavoring agents:
 - (i) are therapeutically inert; and
 - (ii) do not exceed 5% of a preparation's total volume.
- (14) "Consulting pharmacist" means a licensed pharmacist who provides consultation on an aspect of a pharmaceutical administration facility under Section R156-17b-614c.
- (15) "Cooperative pharmacy warehouse" means a physical location for drugs that acts as a central warehouse and is owned, operated or affiliated with a group purchasing organization (GPO) or pharmacy buying cooperative and distributes those drugs exclusively to its members.
- (16) "Counterfeit prescription drug" has the meaning given that term in 21 USC 321(g)(2).
- (17) "Counterfeiting" means engaging in activities that create a counterfeit prescription drug.

(18) "Dispense," as defined in Subsection 58-17b-102(22), does not include transferring medications for a patient from a legally dispensed prescription for that particular patient into a daily or weekly drug container to facilitate the patient taking the correct medication.

(19) "Designated representative" or "DR" means an individual supervising the licensed facility in accordance with Subsections R156-17b-615(4) and (5).

(20) "Device" means a prescription device as defined in 21 CFR 801.109 (2021).

(21) "DMP" means a dispensing medical practitioner licensed under Title 58, Chapter 17b, Part 8, Dispensing Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy.

(22) "DMP designee" means an individual, acting under the direction of a DMP, who:

(a)(i) holds an active health care professional license under one of the following chapters:

(A) Chapter 67, Utah Medical Practice Act;

(B) Chapter 68, Utah Osteopathic Medical Practice Act;

(C) Chapter 70a, Physician Assistant Act;

(D) Chapter 31b, Nurse Practice Act;

(E) Chapter 16a, Utah Optometry Practice Act;

(F) Chapter 44a, Nurse Midwife Practice Act; or

(G) Chapter 17b, Pharmacy Practice Act; or

(ii) is a medical assistant as defined in Subsection 58-67-102(12);

(b) meets requirements in Subsection 58-17b-803 (4)(c); and

(c) can document successful completion of a formal or on-the-job dispensing training program under Section R156-17b-622.

(23) "DMPIC" means a dispensing medical practitioner in charge licensed under Title 58, Chapter 17b, Part 8, Dispensing Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy who is designated by a dispensing medical practitioner clinic pharmacy to be responsible for activities of the pharmacy.

(24) "Drop shipment" means the sale of a prescription drug to a pharmaceutical wholesaler by the manufacturer of the drug; by the manufacturer's co-licensed product partner, third party logistics provider, or exclusive distributor; or by an authorized distributor of record that purchased the product directly from the manufacturer or from one of these entities; whereby:

(a) the pharmaceutical wholesale distributor takes title to but not physical possession of such prescription drug;

(b) the pharmaceutical wholesale distributor invoices the pharmacy, pharmacy warehouse, or other person authorized by law to dispense to administer such drug; and

(c) the pharmacy, pharmacy warehouse, or other person authorized by law to dispense or administer such drug receives delivery of the prescription drug directly from the manufacturer; from the co-licensed product partner, third party logistics provider, or exclusive distributor; or from an authorized distributor of record that purchases the product directly from the manufacturer or from one of these entities.

(25) "Drug therapy management" means the review of a drug therapy regimen of a patient by one or more pharmacists evaluating and rendering advice to one or more practitioners regarding adjustment of the regimen.

(26) "Drugs," as used in this rule, means drugs or devices.

(27) "Durable medical equipment" or "DME" means equipment that:

(a) can withstand repeated use;

(b) is primarily and customarily used to serve a medical purpose;

(c) generally is not useful to a person in the absence of an illness or injury;

(d) is suitable for use in a health care facility or in the home; and

(e) may include devices and medical supplies.

(28) "Entities under common administrative control" means an entity holds the power, actual as well as legal, to influence the management, direction, or functioning of a business or organization.

(29) "Entities under common ownership" means entity assets are held indivisibly rather than in the names of individual members.

(30) "ExCPT" means the Exam for the Certification of Pharmacy Technicians.

(31) "FDA" means the United States Food and Drug Administration and any successor agency.

(32) "FDA-Approved" means the federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. Section 301 et seq. and regulations promulgated thereunder permit the subject drug or device to be lawfully manufactured, marketed, distributed, and sold.

(33) "High-risk, medium-risk, and low-risk drugs" refers to the risk level to a patient's health from compounding sterile preparations, as referred to in USP-NF Chapter 797.

(34) "Hospice facility pharmacy" means a pharmacy that supplies drugs to patients in a licensed healthcare facility for terminal patients.

(35) "Hospital clinic pharmacy" means a pharmacy that is located in an outpatient treatment area where a pharmacist or pharmacy intern is compounding, admixing, or dispensing prescription drugs, and where:

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

(b) prescription drugs or devices are dispensed by the pharmacist or pharmacy intern; or

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

(36) "Legend drug" or "prescription drug" means a drug or device that has been determined to be unsafe for self-medication or one that bears or is required to bear the legend:

- (a) "Caution: federal law prohibits dispensing without prescription";
- (b) "Caution: federal law restricts this drug to use by or on the order of a licensed veterinarian"; or
- (c) "Rx only".

(37) "Long-term care facility" as used in Section 58-17b-610.7 means the same as defined in Section 58-31b-102.

(38) "Maintenance medications" means medications the patient takes on an ongoing basis.

(39)(a) "Manufacturer's exclusive distributor" means an entity that contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer and who takes title to that manufacturer's prescription drug, but who does not have general responsibility to direct the drug's sale or disposition.

(b) A manufacturer's exclusive distributor shall be licensed as a pharmaceutical wholesaler and be an "authorized distributor of record" to be considered part of the normal distribution channel.

(40) "Medical supplies" means items for medical use that are:

- (a) suitable for use in a health care facility or in the home; and
- (b) disposable or semi-disposable and non-reusable.

(41) "MPJE" means the Multistate Jurisprudence Examination.

(42) "NABP" means the National Association of Boards of Pharmacy.

(43) "NAPLEX" means North American Pharmacy Licensing Examination.

(44) "Non-drug or device handling central prescription processing pharmacy" means a central prescription processing pharmacy that does not engage in compounding, packaging, labeling, dispensing, or administering of drugs or devices.

(45) "Normal distribution channel" means a chain of custody for a prescription drug that goes directly, by drop shipment as defined in Subsection (24), or via intracompany transfer from a manufacturer; or from the manufacturer's co-licensed partner, third party logistics provider, or the exclusive distributor, to:

- (a) a pharmacy or other designated persons authorized to dispense or administer prescription drugs to a patient;
- (b) a chain pharmacy warehouse that performs intracompany sales or transfers of such drugs to a group of pharmacies under common ownership and control;
- (c) a cooperative pharmacy warehouse to a pharmacy that is a member of the pharmacy buying cooperative or GPO to a patient;
- (d) an authorized distributor of record, and then to either a pharmacy or other designated persons authorized to dispense or administer such drug for use by a patient;
- (e) an authorized distributor of record, and then to a chain pharmacy warehouse that performs intracompany sales or transfers of such drugs to a group of pharmacies under common ownership and control; or
- (f) an authorized distributor of record to another authorized distributor of record to a licensed pharmaceutical facility or a licensed healthcare practitioner authorized to dispense or administer such drug for use by a patient.

(46) "Other health care facilities" means an entity as defined in Subsection R432-1-3(55).

(47) "Parenteral" means a method of drug delivery injected into body tissues but not via the gastrointestinal tract.

(48) "Patient's agent" means a:

- (a) relative, friend, or other authorized designee of the patient involved in the patient's care; or
- (b) if requested by the patient or the individual under Subsection (45)(a), one of the following facilities:
 - (i) an office of a licensed prescribing practitioner in Utah;
 - (ii) a long-term care facility where the patient resides; or
 - (iii) a hospital, office, clinic or another medical facility that provides health care services.

(49) "Pedigree" means a document or electronic file containing information that records each distribution of any given prescription drug.

(50) "PIC," as used in this rule, means the pharmacist-in-charge.

(51) "Prepackaged" or "Prepackaging" means the act of transferring a drug, manually or by use of an automated pharmacy system, from a manufacturer's or distributor's original container to another container in advance of receiving a prescription drug order or for a patient's immediate need for dispensing by a pharmacy or practitioner authorized to dispense in the establishment where the prepackaging occurred.

(52) "Prescription files" means hard copy and electronic prescriptions that includes pharmacist notes or technician notes, clarifications or information written or attached that is pertinent to the prescription.

(53) "Professional entry degree," as used in Subsection 58-17b-303(1)(f), means the professional entry degree offered by the applicant's ACPE-accredited school or college of pharmacy in the applicant's year of graduation, either a baccalaureate in pharmacy (BSPharm) or a doctorate in pharmacy (PharmD).

(54) "PTCB" means the Pharmacy Technician Certification Board.

(55) "Qualified continuing education", as used in this rule, means continuing education that meets the standards set forth in Section R156-17b-309.

(56) "Refill" means to fill again.

(57) "Remote dispensing pharmacist-in-charge" or "RDPIC" means the PIC of a remote dispensing pharmacy. The RDPIC shall be the PIC of the remote dispensing pharmacy's supervising pharmacy.

(58) "Remote dispensing pharmacy" means a Class A or Class B pharmacy located in Utah that serves as the originating site where a patient receiving services through a telepharmacy system is physically located and the practice of telepharmacy occurs, pursuant to Section R156-17b-614g.

(59) "Repackage" means repackaging or otherwise changing the container, wrapper, or labeling to further the distribution of a prescription drug, excluding that completed by the pharmacist or DMP responsible for dispensing the product to a patient.

(60) "Research facility" means a facility where research takes place that has policies and procedures describing such research.

(61) "Responsible party" means the identity of the supervisor or director or the Class E pharmacy under Section R156-17b-617a.

(62) "Reverse distributor" means a person or company that retrieves unusable or outdated drugs from a pharmacy by removing those drugs from stock and destroying them.

(63) "Self-administered hormonal contraceptive" means the same as defined in Subsection 26-64-102(9).

(64) "Sterile products preparation facility" means any facility, or portion of the facility, that compounds sterile products using aseptic technique.

(65) "Supervising pharmacy" means the Class A or Class B pharmacy responsible for overseeing the operation of a remote dispensing pharmacy, and whose PIC is the RDPIC for the remote dispensing pharmacy, pursuant to Section R156-17b-614g.

(66) "Supervisor" means a licensed pharmacist or DMP in good standing with the Division.

(67) "Telepharmacy system" means a telecommunications and information technologies system that monitors the preparation and dispensing of prescription drugs and provides for related drug review and HIPAA-compliant patient counseling services using:

(a) asynchronous store and forward transfer as defined in Subsection 26-60-102(1);

(b) synchronous interaction as defined in Subsection 26-60-102(7); or

(c) still image capture.

(68) "Third party logistics provider" means anyone who contracts with a prescription drug manufacturer to provide or coordinate warehousing, distribution, or other similar services on behalf of a manufacturer, but does not take title to the prescription drug or have any authoritative control over the prescription drug's sale.

(69) "Unauthorized personnel" means a person not participating in the operational processes of the pharmacy who in some way would interrupt the natural flow of pharmaceutical care.

(70) "Unit dose" means the ordered amount of a drug in a dosage form prepared for a one-time administration to an individual and indicates the name, strength, lot number and beyond use date for the drug.

(71) "Unprofessional conduct," as defined in Title 58, Chapter 1, Division of Occupational and Professional Licensing Act, and Title 58, Chapter 17b, Pharmacy Practice Act, is further defined, in accordance with Subsection 58-1-203(1)(e), in Section R156-17b-502.

(72) The "Utah Hormonal Contraceptive Self-screening Risk Assessment Questionnaire," adopted September 18, 2018, by the Division in collaboration with the Utah State Board of Pharmacy and Physicians Licensing Board, which is incorporated by reference, is the self-screening risk assessment questionnaire approved by the Division pursuant to Section 26-64-106.

(73) "USP-NF" means the United States Pharmacopeia-National Formulary (USP 41-NF 36), either First Supplement, dated August 1, 2018, or Second Supplement, dated December 1, 2018, which is hereby adopted and incorporated by reference.

(74) "Vaccine Administration Protocol" means the Vaccine Administration Protocol: Standing Order to Administer Immunizations and Emergency Medications, adopted September 24, 2020, by the Division in collaboration with the Board and Utah Physicians Licensing Board, which is incorporated by reference.

(75) "Wholesaler" means a wholesale distributor who supplies or distributes drugs or medical devices that are restricted by federal law to sales based on the order of a physician to a person other than the consumer or patient.

(76) "Wholesale distribution" means the same as 21 CFR 203.3(cc) (2021).

R156-17b-103. Authority - Purpose.

This rule is adopted by the Division under the authority of Subsection 58-1-106(1)(a) to enable the Division to administer Title 58, Chapter 17b.

R156-17b-104. Organization - Relationship to Rule R156-1.

The organization of this rule and its relationship to Rule R156-1 is as described in Section R156-1-107.

R156-17b-105. Licensure - Administrative Inspection.

In accordance with Subsection 58-17b-103(3)(f), the procedure for disposing of drugs or devices seized by the Division during an administrative inspection is as follows:

(1) Legal drugs or devices that the Division finds to be in compliance with Title 58, Chapter 17b, Pharmacy Practice Act, shall be returned to the involved pharmacy's consulting pharmacist, designated representative, responsible party, PIC, RDPIC, or DMPIC, at the conclusion of the investigative or adjudicative proceedings and appeals.

(2)(a) Drugs or devices that the Division finds to be unlawfully possessed, adulterated, misbranded, outdated, or otherwise in violation of Title 58, Chapter 17b, Pharmacy Practice Act, shall be destroyed by Division personnel at the conclusion of the investigative or adjudicative proceedings and appeals.

(b) The destruction of seized controlled substance drugs shall be witnessed by two Division individuals. A controlled substance destruction form shall be completed and retained by the Division.

(3) An investigator may, upon determination that the violations observed pose an imminent peril to the public health, safety and welfare, recommend to the Division Director to issue an emergency licensure action, such as cease and desist.

R156-17b-106. Clarification of Use of Shall or May.

As used in Title 58, Chapters 1 and 17b or this rule, the use of "shall" and "may" is clarified as follows:

(1) "May" is permissive, and is used when granting a right, privilege, or power, or indicating any discretion to act.

(2) "Shall" creates a legal duty or obligation on the part of the subject. The statute or rule is mandating that the person act as required by the statute or rule, and the person has no discretion to act differently.

(3) When used negatively:

(a) "may not" is prohibitory, and absolutely prohibits the subject of the statute or rule from performing a particular act; it annihilates discretion; and

(b) "shall not" is a construction not used in drafting Utah statute or rule.

R156-17b-203. Advisory Pharmacy Compounding Education Committee Created - Membership - Duties.

(1) In accordance with Subsection 58-1-203(1)(f) and Section R156-1-205, there is created the Advisory Pharmacy Compounding Education Committee ("Committee").

(2) The Committee shall consist of seven members, diversified between:

(a) retail pharmacy;

(b) hospital pharmacy;

(c) other pharmacy specialties determined pertinent by the Division in collaboration with the Board; and

(d) at least one physician.

(3) Each Committee member shall:

(a) be licensed in good standing with the state; and

(b) have experience and knowledge of least one USP Chapter, USP <795>, USP <797>, or USP <800>.

(4) The Board shall nominate Committee members for appointment in accordance with R156-1-205, and if possible at least six months prior to the date of cessation of service.

(5) The Committee's duties and responsibilities shall be to address pharmacy compounding issues, including:

(a) monitoring current and proposed federal standards and USP standards for pharmacy compounding; and

(b) reviewing and making recommendations to the Division and boards regarding:

(i) pharmacy compounding education and training;

(ii) pharmacy compounding laws and rules; and

(iii) other pharmacy compounding issues as assigned by the Division in collaboration with the Board.

(6) The Committee shall meet at least once per calendar quarter, and as may be directed by the Board with the concurrence of the Division.

(7) The Committee shall annually designate one of its members to act as chair and another member to act as vice chair, on a calendar year basis. The Committee shall elect its chair and vice chair at a meeting conducted in the last quarter of the calendar year.

(8) Each calendar quarter, a Committee designee shall attend at least one Board meeting of each of the following boards to report the Committee's activities and recommendations to the Board and the Division:

(a) the Board of Pharmacy;

(b) the Physicians Licensing Board; and

(c) the Osteopathic Physicians and Surgeons Licensing Board.

R156-17b-302. Pharmacy Licensure Classifications - Pharmacist-in-Charge, Remote Dispensing Pharmacist-in-Charge, or Dispensing Medical Practitioner-In-Charge Requirements.

In accordance with Section 58-17b-302, the classification of pharmacies is clarified as follows:

(1) A Class A pharmacy includes all retail operations located in Utah. A Class A pharmacy requires a PIC or RDPIC. Examples of Class A pharmacies include:

(a) retail pharmacies;

(b) mail service retail pharmacies; and

(c) remote dispensing pharmacies.

(2) A Class B pharmacy includes an institutional pharmacy that provides services to a target population unique to the needs of the healthcare services required by the patient. All Class B pharmacies require a PIC, RDPIC, or DMPIC, except for pharmaceutical administration facilities and narcotic treatment program pharmacies. Examples of Class B pharmacies include:

(a) closed door pharmacies;

(b) hospital clinic pharmacies;

(c) narcotic treatment program pharmacies;

- (d) nuclear pharmacies;
- (e) branch pharmacies;
- (f) hospice facility pharmacies;
- (g) pharmaceutical administration facility pharmacies;
- (h) sterile product preparation facility pharmacies;
- (i) dispensing medical practitioner clinic pharmacies; and
- (j) remote dispensing pharmacies.
- (3) A Class C pharmacy includes a pharmacy that is involved in:
 - (a) manufacturing;
 - (b) producing;
 - (c) wholesaling;
 - (d) distributing; or
 - (e) reverse distributing.
- (4) A Class D pharmacy requires a PIC licensed in the state where the pharmacy is located and includes an out-of-state mail service pharmacy. Facilities with multiple locations shall have licenses for each facility and each component part of a facility.
- (5) A Class E pharmacy does not require a PIC and includes:
 - (a) analytical laboratory pharmacies;
 - (b) animal control pharmacies;
 - (c) durable medical equipment provider pharmacies;
 - (d) human clinical investigational drug research facility pharmacies;
 - (e) medical gas provider pharmacies;
 - (f) animal narcotic detection training facility pharmacies
 - (g) third party logistics providers;
 - (h) non drug or device handling central prescription processing pharmacies; and
 - (i) veterinarian pharmaceutical facility pharmacies.
- (6) The Division shall convert all pharmacy licenses to the appropriate classification as identified in Section 58-17b-302.
- (7) Each Class A and each Class B pharmacy required to have a PIC or DMPIC shall have one PIC or DMPIC who is employed on a full-time basis as defined by the employer, who acts as a PIC or DMPIC for one pharmacy. However, the PIC or DMPIC:
 - (a) may be the PIC or DMPIC of more than one Class A or Class B pharmacy, if the additional Class A or Class B pharmacies are not open to provide pharmacy services simultaneously; and
 - (b) may serve as an RDPIC.
- (8) A PIC, RDPIC, or DMPIC shall comply with Section R156-17b-603.

R156-17b-303a. Qualifications for Licensure - Education Requirements.

- (1) In accordance with Subsections 58-17b-303(2) and 58-17b-304(6)(b), the credentialing agency recognized to provide certification and evaluate equivalency of a foreign educated pharmacy graduate is the Foreign Pharmacy Graduate Examination Committee (FPGEC) of the National Association of Boards of Pharmacy Foundation.
- (2) In accordance with Subsection 58-17b-304(6), an applicant for a pharmacy intern license shall demonstrate that the applicant meets one of the following education criteria:
 - (a) current admission in a college of pharmacy accredited by the ACPE, by written verification from a dean of the college;
 - (b) a graduate degree from a school or college of pharmacy that is accredited by the ACPE; or
 - (c) a graduate degree from a foreign pharmacy school as established by a certificate of equivalency from an approved credentialing agency defined in Subsection (1).
- (3) In accordance with Subsection 58-17b-305(1)(f), a pharmacy technician shall complete a training program that is:
 - (a) accredited by ASHP; or
 - (b) conducted by:
 - (i) the National Pharmacy Technician Association;
 - (ii) Pharmacy Technicians University; or
 - (iii) a branch of the Armed Forces of the United States, and
 - (c) meets the following standards:
 - (i) completion of at least 180 hours of directly supervised practical training in a licensed pharmacy as determined appropriate by a licensed pharmacist in good standing; and
 - (ii) written protocols and guidelines for the teaching pharmacist outlining the utilization and supervision of pharmacy technician trainees that address:
 - (A) the specific manner in which supervision will be completed; and
 - (B) an evaluative procedure to verify the accuracy and completeness of any act, task and function performed by the pharmacy technician trainee.
- (4) An individual shall complete a pharmacy technician training program and successfully pass the required examination as listed in Subsection R156-17b-303c(4) within two years after obtaining a pharmacy technician trainee license, unless otherwise approved by the Division in collaboration with the Board for good cause showing exceptional circumstances.

(a) Unless otherwise approved under Subsection (4), an individual who fails to apply for and obtain a pharmacy technician license within the two-year time frame shall repeat a pharmacy technician training program in its entirety if the individual pursues licensure as a pharmacy technician.

(5)(a) Pharmacy technician training programs that received Division approval on or before April 30, 2014 are exempt from satisfying standards in Subsection R156-17b-303a(3) for students enrolled on or before December 31, 2018.

(b) A student in a program described in Subsection (5)(a) shall comply with the program completion deadline and testing requirements in Subsection (4), except that the license application shall be submitted to the Division no later than December 31, 2021.

(c) A program in ASHP candidate status shall notify a student prior to enrollment that if the program is denied accreditation status while the student is enrolled in the program, the student will be required to complete education in another program with no assurance of how many credits will transfer to the new program.

(d) A program in ASHP candidate status that is denied accreditation shall immediately notify the Division, enrolled students and student practice sites, of the denial. The notice shall instruct each student and practice site that:

(i) the program no longer satisfies the pharmacy technician license education requirement in Utah; and

(ii) enrollment in a different program meeting requirements established in Subsection R156-17b-303a(3) is necessary for the student to complete training and to satisfy the pharmacy technician license education requirement in Utah.

(6) An applicant from another jurisdiction seeking licensure as a pharmacy technician in Utah meets the qualifications for licensure in Subsection 58-17b-305(1)(e) and 58-17b-305(1)(f) if the applicant:

(a) has engaged in the practice of a pharmacy technician for a minimum of 1,000 hours in that jurisdiction within the past two years or has equivalent experience as approved by the Division in collaboration with the Board; and

(b) has passed and maintained current PTCB or ExCPT certification.

R156-17b-303b. Qualifications for Licensure - Pharmacist - Pharmacy Internship Standards.

(1) In accordance with Subsection 58-17b-303(1)(f), the pharmacy internship standards required for licensure as a pharmacist are established in this section.

(2) A graduate of a U.S. pharmacy school shall have at least 1,740 hours of practice obtained according to the Accreditation Council for Pharmacy Education (ACPE), Accreditation Standards and Key Elements for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree, effective July 1, 2016 ("Standards 2016"), which is hereby incorporated by reference.

(3)(a) A graduate of a foreign pharmacy school shall have at least 1,440 hours of supervised pharmacy practice in the United States.

(b) The Division in collaboration with the Board may credit up to 500 hours towards the requirement of Subsection (3)(a) for a graduate's other experience substantially related to the practice of pharmacy.

(4) If a pharmacy intern is suspended or dismissed from an approved College of Pharmacy, the pharmacy intern shall notify the Division within 15 days of the suspension or dismissal.

(5) If a pharmacy intern ceases to meet each requirement for intern licensure, the pharmacy intern shall surrender the pharmacy intern license to the Division within 60 days unless an extension is requested and granted by the Division in collaboration with the Board.

R156-17b-303c. Qualifications for Licensure - Examinations.

(1) In accordance with Subsection 58-17b-303(1)(g), the examinations that shall be passed by an applicant for licensure as a pharmacist are:

(a) the NAPLEX with a passing score as established by NABP; and

(b) the Utah Multistate Pharmacy Jurisprudence Examination(MPJE) with a minimum passing score as established by NABP.

(2)(a) An individual who has failed either examination three times shall meet with the Board to request an additional authorization to test.

(b) The Division, in collaboration with the Board, may require additional training as a condition for approval of an authorization to retest.

(3) In accordance with Subsection 58-17b-303(3)(i), an applicant applying by endorsement shall pass the Utah MPJE.

(4)(a) In accordance with Subsection 58-17b-305(1)(f), an applicant applying for licensure as a pharmacy technician shall pass the PTCB or ExCPT with a passing score as established by the certifying body.

(b) The certificate shall exhibit a valid date and that the certification is active.

(5) A graduate of a foreign pharmacy school shall obtain a passing score on the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination.

R156-17b-303d. Qualifications for Licensure - Meet with the Board.

In accordance with Subsections 58-1-202(1)(d) and 58-1-301(3), an applicant for licensure under Title 58, Chapter 17b may be required to meet with the Board of Pharmacy for the purpose of evaluating the applicant's qualifications for licensure.

R156-17b-304. Temporary Pharmacist Licensure - Additional Authorization to Test.

(1) In accordance with Subsection 58-1-303(1), the Division may issue a temporary pharmacist license to a person who meets all qualifications for licensure as a pharmacist in Utah except for the passing of the required examination, if the applicant:

- (a) is:
 - (i) a graduate of an ACPE accredited pharmacy school within two months immediately preceding application for licensure;
 - (ii) enrolled in a pharmacy graduate residency or fellowship program; or
 - (iii) licensed in good standing to practice pharmacy in another state or territory of the United States;
 - (b) submits a complete application for licensure as a pharmacist except the passing of the NAPLEX and Utah MJPE examinations;
 - (c) submits evidence of having secured employment in Utah conditioned upon issuance of the temporary license, and the employment is under the direct, on-site supervision of a pharmacist with an active, non-temporary Utah license that includes a controlled substance license; and
 - (d) has registered to take the required licensure examinations.
- (2) A temporary pharmacist license issued under Subsection (1) expires the earlier of:
- (a) six months from the date of issuance;
 - (b) the date upon which the Division receives notice from the examination agency that the individual has failed either examination three times; or
 - (c) the date upon which the Division issues the individual full licensure.
- (3) An individual who has failed either examination three times shall meet with the Board to request an additional authorization to test. The Division, in collaboration with the Board, may require additional training as a condition for approval of an authorization to retest.
- (4) A pharmacist temporary license issued in accordance with this section cannot be renewed, but may be extended up to six months, as approved by the Division in collaboration with the Board.

R156-17b-307. Qualifications for Licensure - Criminal Background Checks.

- (1) An applicant for licensure as a pharmacy shall document, to the satisfaction of the Division, the owners and management of the pharmacy and the facility in which the pharmacy is located.
- (2) The following individuals associated with an applicant for licensure as a pharmacy shall be subject to the criminal background check requirements set forth in Section 58-17b-307:
- (a) the PIC;
 - (b) the PIC's immediate supervisor;
 - (c) the senior person in charge of the facility in which the pharmacy is located;
 - (d) others associated with management of the pharmacy or the facility in which the pharmacy is located as determined necessary by the Division in order to protect public health, safety and welfare; and
 - (e) owners of the pharmacy or the facility in which the pharmacy is located as determined necessary by the Division in order to protect public health, safety and welfare.

R156-17b-308. Term, Expiration, Renewal, and Reinstatement of License - Application Procedures.

In accordance with Sections 58-1-308 and 58-17b-506:

- (1) The renewal date for the two-year renewal cycle applicable to licensees under Title 58, Chapter 17b is established in Section R156-1-308a.
- (2) Renewal and reinstatement procedures shall be in accordance with Sections R156-1-308a through R156-1-308I, except as provided in Subsection (3).
- (3) An applicant whose license was active and in good standing at the time of expiration may apply for reinstatement between two years and eight years after the date of expiration, in accordance with the following practice re-entry requirements:
- (a) Each applicant shall:
 - (i) submit a reinstatement application demonstrating compliance with all requirements and conditions of license renewal;
 - (ii) pay all license renewal and reinstatement fees for the current renewal period; and
 - (iii) comply with any additional licensure requirements or conditions considered necessary by the Division in collaboration with the Board to protect the public and ensure the applicant is currently competent to engage in the profession, such as:
 - (A) a background check;
 - (B) conditional licensure;
 - (C) refresher or practice re-entry programs;
 - (D) licensure exams;
 - (E) supervised practice requirements;
 - (F) fitness for duty/competency evaluations; or
 - (G) any other licensure requirements or conditions determined necessary by the Division in collaboration with the Board.
 - (b) An applicant applying between two and five years after expiration shall also:
 - (i) if requested, meet with the Board for evaluation of the applicant's qualifications for licensure; and
 - (ii) submit evidence that the applicant has successfully completed:
 - (A) all continuing education for each preceding renewal period in which the license was expired; or
 - (B) a refresher or practice re-entry program approved by the Division in collaboration with the Board.
 - (c) An applicant applying five or more years after expiration shall also:

- (i) meet with the Board for evaluation of the applicant's qualifications for licensure;
- (ii) submit evidence that the applicant has:
 - (A) within five years preceding the application, passed the examinations required for licensure under Section R156-17b-303c (NAPLEX and MPJE for a pharmacist, or PTCB or ExCPT for a pharmacy technician); or
 - (B) successfully completed a refresher or practice re-entry program approved by the Division in collaboration with the Board;
- and
- (iii) successfully practice under conditional licensure during a period of direct supervision by a pharmacist, for a period equal to at least 40 hours of supervision for each expired year.
- (4) The Division in collaboration with the Board may approve extension of an intern license upon the request of the licensee, if the intern lacks the required number of internship hours for licensure.

R156-17b-309. Continuing Education.

In accordance with Section 58-17b-310 and Subsections 58-1-203(1)(g) and 58-1-308(3)(b), the continuing education (CE) requirements for renewal or reinstatement of a pharmacist or pharmacy technician license for each two-year renewal cycle are established as follows:

- (1) A pharmacist shall complete at least 30 CE hours, that shall include at minimum:
 - (a) 12 hours of live or technology-enabled participation in lectures, seminars, or workshops;
 - (b) 15 hours in one or more of the following topics:
 - (i) disease state management-drug therapy;
 - (ii) AIDS therapy;
 - (iii) patient safety; or
 - (iv) immunizations;
 - (c) one hour of pharmacy law or ethics;
 - (d) if engaging in the administration of vaccines as defined in Section R156-17b-621, two hours in vaccine-related topics, which hours may be counted as part of the 15 hours required under Subsection (1)(b);
 - (e) if engaging in the administration of prescription drugs or devices as defined in Section R156-17b-621 or R156-17b-625, two hours in topics related to the administration of those prescription drugs or devices; and
 - (f) if dispensing a self-administered hormonal contraceptive in accordance with Title 26, Chapter 62, Family Planning Access Act as defined in R156-17b-621b, two hours in topics related to hormonal contraceptive therapy.
- (2)(a) A pharmacy technician shall complete at least 20 CE hours, which shall include at minimum:
 - (i) six hours of live or technology-enabled participation at lectures, seminars, or workshops;
 - (ii) one hour of pharmacy law or ethics; and
 - (iii) if engaging in the administration of vaccines as defined in Section R156-17b-621, two hours in vaccine-related topics.
- (b) Current PTCB or ExCPT certification shall fulfill each CE requirements for a pharmacy technician, except for vaccine-related topic hours that may be required under Subsection (2)(a)(iii).
- (3)(a) If a licensee first becomes licensed during the two-year renewal cycle, the licensee's required number of CE hours shall be decreased proportionately according to the date of licensure.
- (b) The Division may defer or waive each CE requirements as provided in Section R156-1-308d.
- (4) CE credit shall be recognized as follows:
 - (a) One live CE hour for attending one Utah State Board of Pharmacy meeting, up to a maximum of two CE hours during each two-year period. These hours may count as "pharmacy law or ethics" hours.
 - (b) Two CE hours for each hour of lecturing or instructing a CE course or teaching in the licensee's profession, up to a maximum of ten CE hours during each two-year period. The licensee shall document the course's content and intended audience (e.g., pharmacists, pharmacy technicians, pharmacy interns, physicians, nurses). Public service programs, such as presentations to schoolchildren or service clubs, are not eligible for CE credit.
 - (c) CE credit shall be approved by, conducted by, or under the sponsorship of one of the following:
 - (i) institutes, seminars, lectures, conferences, workshops, various forms of mediated instruction, and programmed learning courses, presented by an ACPE-approved institution, individual, organization, association, corporation, or agency;
 - (ii) programs approved by health-related CE approval organizations, provided the CE is nationally recognized by a healthcare accrediting agency and is related to the practice of pharmacy;
 - (iii) Division training or educational presentations;
 - (iv) educational meetings that are ACPE accredited and are sponsored by the Utah Pharmacy Association, the Utah Society of Health-System Pharmacists, or other professional organization or association; and
 - (v) for pharmacists, programs of certification by qualified individuals such as certified diabetes educator credentials, board certification, or other certification as approved by the Division in collaboration with the Board.
- (5) A licensee shall maintain documentation sufficient to prove compliance with this section, for a period of four years after the end of the renewal cycle for which the CE is due, by:
 - (a) maintaining registration with the NABP e-Profile CPE Monitor plan or the NABP CPE Monitor Plus plan; and
 - (b) maintaining a certificate of completion or other adequate documentation for CE that cannot be tracked by the licensee's NABP plan.

R156-17b-309.7. Exemptions from Licensure - Opioid Treatment Program.

(1) In accordance with Section 58-17-b-309.7 "under the direction of a pharmacist" means that the pharmacist has delegated to a covered provider the authority to perform one or more selected dispensing tasks on behalf of the pharmacist:

- (a) in accordance with state and federal laws and rules; and
- (b) under the general supervision of the pharmacist as defined in Subsection R156-1-102a(4)(c).

(2) A pharmacist retains accountability for the appropriate delegation of dispensing tasks.

(3) The covered provider is accountable for the accuracy of the dispensing task and shall consult the pharmacist as needed.

(4) A covered provider may not:

- (a) further delegate to another person any dispensing task delegated to the covered provider by the pharmacist; or
- (b) expand the scope of a delegated dispensing task without the express permission of the pharmacist.

R156-17b-401. Disciplinary Proceedings.

(1) An individual licensed as a pharmacy intern who is currently under disciplinary action and qualifies for licensure as a pharmacist may be issued a pharmacist license under the same restrictions as the pharmacy intern license.

(2) A pharmacist, pharmacy intern, pharmacy technician, pharmacy technician trainee, or DMP whose license or registration is suspended under Subsection 58-17b-701(6) may petition the Division at any time to demonstrate the ability to resume competent practice.

R156-17b-402. Administrative Penalties.

In accordance with Subsection 58-17b-401(6) and Sections 58-17b-501 and 58-17b-502, unless otherwise ordered by the presiding officer, the following fine and citation schedule shall apply:

TABLE

FINE SCHEDULE

VIOLATION	FIRST OFFENSE	SUBSEQUENT OFFENSE
58-1-501(1)(a)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
58-1-501(1)(b)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
58-1-501(1)(c)	\$ 500 - \$ 1,000	\$ 1,000 - \$ 5,000
58-1-501(1)(d)	\$ 500 - \$ 1,000	\$ 1,000 - \$ 5,000
58-1-501(1)(e)	\$ 100 - \$ 2,000	\$ 2,000 - \$10,000
58-1-501(1)(f)(i)(A) \$	500 - \$ 2,000	\$ 2,000 - \$10,000
58-1-501(2)(m)(i)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
58-1-501(1)(f)(i)(B) \$	500 - \$ 2,000	\$ 2,000 - \$10,000
58-1-501(2)(m)(ii)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
58-1-501(2)(a)	\$ 100 - \$ 2,000	\$ 2,000 - \$10,000
58-1-501(2)(b)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
58-1-501(2)(c)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
58-1-501(2)(d)	\$ 100 - \$ 500	\$ 200 - \$ 1,000
58-1-501(2)(e)	\$ 100 - \$ 500	\$ 200 - \$ 1,000
58-1-501(2)(f)	\$ 100 - \$ 500	\$ 200 - \$ 1,000
58-1-501(2)(g)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
58-1-501(2)(h)	\$ 100 - \$ 500	\$ 200 - \$ 1,000
58-1-501(2)(i)	\$ 100 - \$ 500	\$ 200 - \$ 1,000
58-1-501(2)(j)	\$ 100 - \$ 500	\$ 200 - \$ 1,000
58-1-501(2)(k)	\$ 100 - \$ 1,000	\$ 500 - \$ 2,000
58-1-501(2)(l)	\$ 100 - \$ 500	\$ 200 - \$ 1,000
58-1-501(2)(n)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
58-1-501.5	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
R156-1-501(1)	\$ 500 - \$ 2,000	\$ 2,500 - \$10,000
R156-1-501(2)	\$ 500 - \$ 2,000	\$ 2,500 - \$10,000
R156-1-501(3)	\$ 500 - \$ 2,000	\$ 2,500 - \$10,000
R156-1-501(4)	\$ 500 - \$ 2,000	\$ 2,500 - \$10,000
R156-1-501(5)	\$ 500 - \$ 2,000	\$ 2,500 - \$10,000
R156-1-501(6)	\$ 500 - \$ 2,000	\$ 2,500 - \$10,000
58-17b-501(1)	\$ 500 - \$ 2,000	\$ 5,000
58-17b-501(2)	\$ 100 - \$ 1,000	\$ 500 - \$ 2,000
58-17b-501(3)(a)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
58-17b-501(3)(b)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
58-17b-501(4)	\$ 1,000 - \$ 5,000	\$10,000
58-17b-501(5)	\$ 100 - \$ 500	\$ 200 - \$ 1,000
58-17b-501(6)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
58-17b-501(7)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
58-17b-501(8)	\$ 500 - \$ 2,000	\$ 2,500 - \$10,000
58-17b-501(9)	\$ 500 - \$ 1,000	\$ 1,500 - \$ 5,000
58-17b-501(10)	\$ 500 - \$ 2,000	\$ 2,500 - \$10,000
58-17b-501(11)	\$ 500 - \$ 2,000	\$ 2,500 - \$10,000
58-17b-501(12)	\$ 1,000 - \$ 5,000	\$10,000

58-17b-501(13)	\$ 100 - \$ 500	\$ 1,000 - \$ 2,500
58-17b-502(1)(a)	\$ 500 - \$ 2,000	\$ 2,500 - \$10,000
58-17b-502(1)(b)	\$ 2,500 - \$ 5,000	\$ 5,500 - \$10,000
58-17b-502(1)(c)	\$ 1,000 - \$ 5,000	\$10,000
58-17b-502(1)(d)	\$ 500 - \$ 2,000	\$ 2,500 - \$10,000
58-17b-502(1)(e)	\$ 1,000 - \$ 5,000	\$10,000
58-17b-502(1)(f)	\$ 500 - \$ 2,000	\$ 2,500 - \$10,000
58-17b-502(1)(g)	\$ 500 - \$ 2,000	\$ 2,500 - \$10,000
58-17b-502(1)(h)	\$ 100 - \$ 500	\$ 500 - \$ 1,000
58-17b-502(1)(i)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
58-17b-502(1)(j)	\$ 100 - \$ 500	\$ 500 - \$ 1,000
58-17b-502(1)(k)	\$ 100 - \$ 500	\$ 2,000 - \$10,000
58-17b-502(1)(l)	\$ 100 - \$ 500	\$ 500 - \$ 1,000
58-17b-502(1)(m)	\$ 500 - \$ 1,000	\$ 2,500 - \$ 5,000
58-17b-502(1)(n)	\$ 100 - \$ 500	\$ 500 - \$ 1,000
58-17b-502(1)(o)	\$ 100 - \$ 500	\$ 500 - \$ 1,000
58-17b-502(1)(p)	\$ 2,500 - \$ 5,000	\$ 5,000 - \$10,000
R156-17b-502(1)	\$ 250 - \$ 500	\$ 2,000 - \$10,000
R156-17b-502(2)(a)	\$ 250 - \$ 500	\$ 500 - \$ 750
R156-17b-502(2)(b)	\$ 500 - \$ 2,000	\$ 2,500 - \$10,000
R156-17b-502(3)	\$ 100 - \$ 500	\$ 500 - \$ 1,000
R156-17b-502(4)	\$ 50 - \$ 100	\$ 200 - \$ 300
R156-17b-502(5)	\$ 100 - \$ 200	\$ 200 - \$ 500
R156-17b-502(6)	\$ 500 - \$ 1,000	\$ 2,000 - \$10,000
R156-17b-502(7)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
R156-17b-502(8)	\$ 100 - \$ 250	\$ 300 - \$ 500
R156-17b-502(9)(a)	\$ 50 - \$ 100	\$ 250 - \$ 500
R156-17b-502(9)(b)	\$ 250 - \$ 500	\$ 750 - \$ 1,000
R156-17b-502(10)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
R156-17b-502(11)	\$ 100 - \$ 500	\$ 500 - \$ 1,000
R156-17b-502(12)(a)	\$ 100 - \$ 250	\$ 500 - \$ 2,500
R156-17b-502(12)(b)	\$ 250 - \$ 1,000	\$ 500 - \$ 5,000
R156-17b-502(13)(a)	\$ 50 - \$ 100	\$ 250 - \$ 500
R156-17b-502(13)(b)	\$ 250 - \$ 500	\$ 1,000 - \$ 2,000
R156-17b-502(14)(a)	\$ 500 - \$2,500	\$ 5,000 - \$10,000
R156-17b-502(14)(b)	\$ 2,000 per occurrence	
R156-17b-502(15)	double original penalty, up to \$10,000	
R156-17b-502(16)	\$ 500 - \$2,000	\$ 2,000 - \$10,000
R156-17b-502(17)	\$ 1,000 - \$5,000	\$10,000
R156-17b-502(18)	\$ 500 - \$2,500	\$ 5,000 - \$10,000
R156-17b-502(19)	\$ 100 - \$500	\$ 200 - \$ 1,000
R156-17b-502(20)	\$ 100 - \$500	\$ 200 - \$ 1,000
R156-17b-502(21)	\$ 100 - \$500	\$ 200 - \$ 1,000
R156-17b-502(22)	\$ 500 - \$2,000	\$ 2,000 - \$10,000
R156-17b-502(23)(a)	\$ 100 - \$300	\$ 500 - \$ 1,000
R156-17b-502(23)(b)	\$ 250 - \$500	\$ 500 - \$ 1,250
R156-17b-502(24)	\$ 100 - \$500	\$ 500 - \$ 1,000
R156-17b-502(25)	\$ 500 - \$2,000	\$ 2,500 - \$10,000
R156-17b-502(26)	\$ 500 - \$2,000	\$ 2,500 - \$10,000
58-37-8	\$ 1,000 - \$5,000	\$ 5,000 - \$10,000
R156-37-502(1)(a)	\$ 500 - \$2,000	\$ 2,500 - \$10,000
R156-37-502(1)(b)	\$ 500 - \$2,000	\$ 2,500 - \$10,000
R156-37-502(2)	\$ 500 - \$2,000	\$ 2,500 - \$10,000
R156-37-502(3)	\$ 500 - \$2,000	\$ 2,500 - \$10,000
R156-37-502(4)	\$ 500 - \$2,000	\$ 2,500 - \$10,000
R156-37-502(5)	\$ 500 - \$2,000	\$ 2,500 - \$10,000
R156-37-502(6)	\$ 500 - \$2,000	\$ 2,500 - \$10,000
R156-37-502(7)	\$ 500 - \$2,000	\$ 2,500 - \$10,000
R156-37-502(8)	\$ 500 - \$2,000	\$ 2,500 - \$10,000
Any other conduct that constitutes Unprofessional or Unlawful conduct	\$ 100 - \$ 500	\$ 200 - \$ 1,000

R156-17b-502. Unprofessional Conduct.

"Unprofessional conduct" includes:

(1) violating the American Pharmaceutical Association (APhA) Code of Ethics for Pharmacists, October 27, 1994, which is hereby incorporated by reference;

(2)(a) failing to comply with the USP-NF Chapter 795 if applicable to activities performed;

(b) failing to comply with the USP-NF Chapter 797, if applicable to activities performed;

(3) failing to comply with continuing education requirements;

(4) failing to provide the Division with a current mailing address within ten business days of a change of address;

(5) defaulting on a student loan;

- (6) failing to abide by applicable federal and state law regarding the practice of pharmacy;
- (7) failing to comply with administrative inspections;
- (8) failing to return a self-audit report by the deadline established by the Division;
- (9) providing false information on a self-audit report;
- (10)(a) violating the laws and rules regulating operating standards in a pharmacy, as discovered upon inspection by the Division; or
- (b) after discovery upon inspection by the Division of violation of laws and rules regulating operating standards in a pharmacy, failing to comply within the time established by the Division;
- (11) abandoning a pharmacy or leaving prescription drugs accessible to the public;
- (12) failing to identify licensure classification when communicating by any means;
- (13)(a) as a pharmacist, practicing pharmacy with an inappropriate pharmacist to pharmacy intern ratio under Subsection R156-17b-606(1)(d), or pharmacist to pharmacy technician trainee ratio under Subsection R156-17b-601(3); or
- (b) as a pharmacy, practicing pharmacy with an inappropriate pharmacist to pharmacy intern ratio under Subsection R156-17b-606(1)(d), or pharmacist to pharmacy technician trainee ratio under Subsection R156-17b-601(4);
- (14)(a) as a pharmacist, allowing an unauthorized person in the pharmacy; or
- (b) as a pharmacy, allowing an unauthorized person in the pharmacy;
- (15)(a) as a pharmacist, failing to offer to counsel a person receiving a prescription medication; or
- (b) as a pharmacy, failing to offer to counsel a person receiving a prescription medication;
- (16) failing to timely pay an administrative fine;
- (17) failing to comply with the PIC, consulting pharmacist, RDPIC or DMPIC standards under Section R156-17b-603;
- (18) failing to adhere to institutional policies and procedures related to technician checking of medications when technician checking is utilized;
- (19) failing to take appropriate steps to avoid or resolve identified drug therapy management problems under Subsection R156-17b-611(3);
- (20) dispensing medication that has been discontinued by the FDA;
- (21) failing to keep or report accurate records of training hours;
- (22) failing to provide consulting pharmacist, designated representative, responsible party, PIC, RDPIC, or DMPIC information to the Division within 30 days of a change in consulting pharmacist, designated representative, responsible party, PIC, RDPIC or DMPIC;
- (23) requiring a pharmacy, pharmacist, or DMP to operate the pharmacy or allow operation of the pharmacy with a ratio of supervising pharmacist or DMP to other pharmacy personnel in circumstances that result in, or reasonably would be expected to result in, an unreasonable risk of harm to public health, safety, and welfare;
- (24)(a) as a pharmacist, failing under Subsection R156-17b-603(3)(t) to notify the Division within seven calendar days of a change in the email address designated for use in self-audits or pharmacy alerts; or
- (b) as a pharmacy, failing to notify the Division within seven calendar days of a change in the email address designated for use in self-audits or pharmacy alerts;
- (25) failing to ensure, as a DMP or DMP clinic pharmacy, that a DMP designee has completed a formal or on-the-job dispensing training program under Section R156-17b-622;
- (26) failing to make a timely report regarding dispensing of an opiate antagonist to the Division and to the physician who issued the standing order, under Section R156-17b-625; and
- (27) failing to comply with the operating standards for a remote dispensing pharmacy under Section R156-17b-614g.

R156-17b-601. Operating Standards - Pharmacy Technician and Pharmacy Technician Trainee.

In accordance with Subsection 58-17b-102(56), practice as a licensed pharmacy technician is defined as follows:

- (1) A pharmacy technician may perform any task associated with the physical preparation and processing of prescription and medication orders, including:
 - (a) receiving written prescriptions;
 - (b) taking refill orders, including refill authorizations;
 - (c) entering and retrieving information into and from a database or patient profile;
 - (d) preparing labels;
 - (e) retrieving medications from inventory;
 - (f) counting and pouring into containers;
 - (g) placing medications into patient storage containers;
 - (h) affixing labels;
 - (i) compounding;
 - (j) counseling for over-the-counter drugs and dietary supplements under the direction of the supervising pharmacist;
 - (k) receiving new prescription drug orders when communicating telephonically or electronically, if the original information is recorded so the pharmacist may review the prescription drug order as transmitted, including accepting new prescription drug orders saved on voicemail for a pharmacist to review;
 - (l) transferring prescriptions under Sections 58-17b-604 and R156-17b-609;

(m) performing checks of certain medications prepared for distribution filled or prepared by another technician within a Class B hospital pharmacy, such as medications prepared for distribution to an automated dispensing cabinet, cart fill, crash cart medication tray, or unit dosing from a prepared stock bottle, in accordance with the following operating standards:

- (i) technicians authorized by a hospital to check medications shall have at least:
 - (A) one year of experience working as a pharmacy technician; and
 - (B) six months of experience at the hospital where the technician is authorized to check medications;
- (ii) technicians shall only check steps in the medication distribution process that do not require the professional judgment of a pharmacist and that are supported by sufficient automation or technology to ensure accuracy, such as barcode scanning, drug identification automation, checklists, visual aids);
- (iii) hospitals that authorize technicians to check medications shall:
 - (A) have a training program and ongoing competency assessment that is documented and retrievable for the duration of each technician's employment and at least three years beyond employment; and
 - (B) maintain a list of technicians on staff that are allowed to check medications;
- (iv) hospitals that authorize technicians to check medications shall have a medication error reporting system in place and shall be able to produce documentation of its use;
- (v) a supervising pharmacist shall be immediately available during times that a pharmacy technician is checking medications; and
- (vi) hospitals that authorize technicians to check medications shall have comprehensive policies and procedures that guide technician checking that include the following:
 - (A) process for technician training and ongoing competency assessment and documentation;
 - (B) process for supervising technicians who check medications;
 - (C) list of medications, or types of medications that may or may not be checked by a technician;
 - (D) description of the automation or technology to be utilized by the institution to augment the technician check;
 - (E) process for maintaining a permanent log of the unique initials or identification codes that identify each technician responsible for checked medications by name; and
 - (F) description of processes used to track and respond to medication errors; and
- (n) additional tasks not requiring the judgment of a pharmacist.
- (2) A pharmacy technician may not:
 - (a) receive a new prescription or medication order, except as described in Subsection (1)(k);
 - (b) clarify a prescription or medication order from a prescriber;
 - (c) perform a drug utilization review;
 - (d) perform final review of a prescribed drug prepared for dispensing;
 - (e) dispense a drug; or
 - (f) counsel a patient with respect to a prescription drug.
- (3) A pharmacy technician may administer vaccines and emergency medications pursuant to delegation by a pharmacist under the Vaccine Administration Protocol, if the pharmacy technician:
 - (a) has completed the initial training required by Section R156-17b-621;
 - (b) is under direct, on-site supervision by the delegating pharmacist as defined in Subsection R156-1-102a(4)(a); and
 - (c) for each renewal cycle after the initial training, has completed a minimum of two hours of continuing education in immunization or vaccine-related topics in accordance with Section R156-17-309.
- (4) A pharmacy technician trainee:
 - (a) shall practice only under the direct supervision of a pharmacist, and in a ratio not to exceed one pharmacy technician trainee to one pharmacist; and
 - (b) may perform any task in Subsection (1), except performing checks of certain medications prepared for distribution filled or prepared by a technician within a Class B hospital pharmacy as described in Subsection (1)(n).

R156-17b-602. Operating Standards - Pharmacy Intern.

A pharmacy intern may provide services including the practice of pharmacy under the supervision of a pharmacist preceptor, if the pharmacy intern met the criteria in Subsection R156-17b-303a.

R156-17b-603. Operating Standards - Consulting Pharmacist, Pharmacist-In-Charge, Remote Dispensing Pharmacist-in-Charge, or Dispensing-Medical-Practitioner-In-Charge.

(1) The consulting pharmacist, PIC, RDPIC, or DMPIC shall have the responsibility to oversee the operation of the pharmacy in conformance with laws and rules pertinent to the practice of pharmacy and the distribution of drugs, durable medical equipment, and medical supplies. The consulting pharmacist, PIC, RDPIC, or DMPIC shall be personally in full and actual charge of the pharmacy.

(2)(a) In accordance with Subsections 58-17b-103(1) and 58-17b-601(1), a unique email address shall be established by the consulting pharmacist, PIC, RDPIC, DMPIC, or responsible party for the pharmacy to be used for self-audits or pharmacy alerts initiated by the Division.

(b) The consulting pharmacist, PIC, RDPIC, DMPIC, or responsible party shall notify the Division of the pharmacy's email address in the initial application for licensure.

(3) The duties of the consulting pharmacist, PIC, RDPIC, or DMPIC shall include:

- (a) assuring that a pharmacist, pharmacy intern, DMP, or DMP designee dispenses drugs or devices, including:
 - (i) packaging, preparation, compounding and labeling; and
 - (ii) ensuring that drugs are dispensed safely and accurately as prescribed;
- (b) assuring that pharmacy personnel deliver drugs to the patient or the patient's agent, including ensuring that drugs are delivered safely and accurately as prescribed;
- (c) assuring that a pharmacist, pharmacy intern, or DMP communicates to the patient or the patient's agent, at their request, information concerning any prescription drugs dispensed to the patient by the pharmacist, pharmacy intern, or DMP;
- (d) assuring that a reasonable effort is made to obtain, record and maintain patient medication records;
- (e) education and training of pharmacy personnel;
- (f) establishment of policies for procurement of prescription drugs and devices and other products dispensed from the pharmacy;
- (g) disposal and distribution of drugs from the pharmacy;
- (h) bulk compounding of drugs;
- (i) storage of materials, including drugs, chemicals and biologicals;
- (j) maintenance of records of transactions of the pharmacy necessary to maintain accurate control over and accountability for pharmaceutical materials required by applicable state and federal laws and regulations;
- (k) establishment and maintenance of effective controls against theft or diversion of prescription drugs and records for such drugs;
- (l) if records are kept on a data processing system, the maintenance of records stored in that system shall be in compliance with pharmacy requirements;
- (m) legal operation of the pharmacy including meeting inspection and other requirements of state and federal laws, rules and regulations governing the practice of pharmacy;
- (n) implementation of an ongoing quality assurance program that monitors performance of the automated pharmacy system, which is evidenced by written policies and procedures developed for pharmaceutical care;
- (o) if permitted to use an automated pharmacy system for dispensing purposes:
 - (i) ensuring that the system is in good working order and accurately dispenses the correct strength, dosage form and quantity of the drug prescribed while maintaining appropriate record keeping and security safeguards; and
 - (ii) implementation of an ongoing quality assurance program that monitors performance of the automated pharmacy system, which is evidenced by written policies and procedures developed for pharmaceutical care;
- (p) assuring that relevant information is submitted to the Controlled Substance Database in the appropriate format and in a timely manner;
- (q) assuring that pharmacy personnel have the appropriate licensure;
- (r) assuring that no pharmacy operates with a ratio of pharmacist or DMP to other pharmacy personnel in circumstances that result in, or reasonably would be expected to result in, an unreasonable risk of harm to public health, safety, and welfare;
- (s) assuring that the consulting pharmacist, PIC, RDPIC, or DMPIC assigned to the pharmacy is recorded with the Division on a form provided by the Division, and that the Division is notified of a change in consulting pharmacist, PIC, RDPIC, or DMPIC within 30 days of the change;
- (t) assuring, with regard to the unique email address used for self-audits and pharmacy alerts, that the pharmacy:
 - (i) uses a single email address; and
 - (ii) notifies the Division, on the form prescribed, of a change in the email address within seven calendar days of the change;
- (u) under Subsection 58-17b-103(1), conducting a pharmacy self-audit on a form provided by the Division, in accordance with the following timeframes:
 - (i) within 30 days of a change of consulting pharmacist, PIC, DMPIC or RDPIC;
 - (ii) within 30 days of the opening of a new facility; and
 - (iii) at least 90 days prior to the end of each renewal cycle; and
 - (iv) maintaining each pharmacy self-audit form for a period of two years from the date of the self-audit.

R156-17b-604. Operating Standards - Closing a Pharmacy.

- (1) The consulting pharmacist, DR, Responsible Party, PIC, RDPIC, or DMPIC of the registered pharmacy shall comply with 21 CFR 1301.52 (2021) and 21 CFR 1305.18 and 1305.19 (2021).
- (2) If the pharmacy dispenses prescription drug orders, post a closing notice sign in a conspicuous place in the front of the prescription department and at public entrance doors to the pharmacy. The closing notice shall contain the following information:
 - (a) the date of closing; and
 - (b) the name, address, and telephone number of the pharmacy acquiring the prescription drug orders, including refill information and patient medication records of the pharmacy.
- (3) On the date of closing, the consulting pharmacist, PIC, RDPIC, or DMPIC shall remove prescription drugs from the pharmacy by one or a combination of the following methods:
 - (a) return prescription drugs to manufacturer or supplier for credit or disposal; or
 - (b) transfer, sell, or give away prescription drugs to a person who is legally entitled to possess drugs, such as a hospital or another pharmacy.

- (4) If the pharmacy dispenses prescription drug orders:
 - (a) transfer the prescription drug order files, including refill information and patient medication records, to a licensed pharmacy within a reasonable distance of the closing pharmacy; and
 - (b) move signs or notify the landlord or owner of the property that it is unlawful to use the word "pharmacy", or any other word or combination of words of the same or similar meaning, or any graphic representation that would mislead or tend to mislead the public that a pharmacy is located at this address.
- (5) Within ten days of the closing of the pharmacy, the pharmacy owner, consulting pharmacist, DR, Responsible Party, PIC, RDPIC, or DMPIC shall forward to the Division a surrender notice, on a form provided by the Division, of the closing that includes the following information:
 - (a) the actual date of closing;
 - (b) a surrender of the license issued to the pharmacy;
 - (c) a statement attesting:
 - (i) that an inventory as specified in Subsection R156-17b-605(4) has been conducted; and
 - (ii) the manner in which the legend drugs and controlled substances possessed by the pharmacy were transferred or disposed; and
 - (d) if the pharmacy dispenses prescription drug orders, the name and address of the pharmacy to which the prescription drug orders, including refill information and patient medication records, were transferred.
- (6) If the pharmacy is closed suddenly due to fire, destruction, natural disaster, death, property seizure, eviction, bankruptcy or other emergency circumstances and the consulting pharmacist, DR, Responsible Party, PIC, RDPIC, or DMPIC cannot provide notification 14 days prior to the closing, the consulting pharmacist, PIC, RDPIC, or DMPIC shall comply with Subsection (1) as far in advance of the closing as allowed by the circumstances.
- (7) If the consulting pharmacist, DR, Responsible Party, PIC, RDPIC, or DMPIC is not available to comply with the requirements of this section, the owner or legal representative shall be responsible for compliance with this section.
- (8) Notwithstanding the requirements of this section, a DMP clinic pharmacy that closes but employs licensed practitioners who will continue providing services other than dispensing may continue to use prescription drugs in their practice as authorized under their respective licensing act.

R156-17b-605. Operating Standards - Inventory Requirements.

- (1) Authorized personnel shall remove out-of-date legend drugs and controlled substances from the inventory at regular intervals and in correlation to the beyond use date imprinted on the label.
- (2) General requirements for inventory of a pharmacy shall include the following:
 - (a) the consulting pharmacist, PIC, RDPIC, or DMPIC shall be responsible for taking required inventories, but may delegate the performance of the inventory to another person or persons;
 - (b) the inventory records shall be maintained for a period of five years and be readily available for inspection;
 - (c) the inventory records shall be filed separately from all other records;
 - (d) the inventory records shall be in a written, typewritten, or printed form and include each stock of controlled substances on hand on the date of the inventory, including any that are out-of-date drugs and drugs in automated pharmacy systems
 - (e) an inventory taken by use of a verbal recording device shall be promptly transcribed;
 - (f) the inventory may be taken either as the opening of the business or the close of business on the inventory date;
 - (g) the person taking the inventory and the consulting pharmacist, PIC, RDPIC, or DMPIC shall indicate the time the inventory was taken and shall sign and date the inventory with the date the inventory was taken;
 - (h) the signature of the consulting pharmacist, PIC, RDPIC, or DMPIC and the date of the inventory shall be documented within 72 hours or three working days of the completed initial, annual, change of ownership and closing inventory;
 - (i) the person taking the inventory shall make an exact count or measure controlled substances listed in Schedule I or II;
 - (j) the person taking the inventory shall make an estimated count or measure of Schedule III, IV, or V controlled substances, unless the container holds more than 1,000 tablets or capsules in which case an exact count of the contents shall be made;
 - (k) the inventory of Schedule I and II controlled substances shall be listed separately from the inventory of Schedule III, IV and V controlled substances;
 - (l) if the pharmacy maintains a perpetual inventory of any of the drugs required to be inventoried, the perpetual inventory shall be reconciled on the date of the inventory.
- (3) Requirements for taking the initial controlled substances inventory shall include the following:
 - (a)(i) pharmacies having stock of controlled substances shall take an inventory, including out-of-date drugs and drugs in automated pharmacy systems, on the opening day of business;
 - (b) if a pharmacy commences business with no Schedule I or II controlled substances, the pharmacy shall record this fact as the initial inventory and shall document Schedule I and II controlled substance inventory separately from an inventory reporting no Schedule III, IV, and V controlled substances;
 - (c) the initial inventory shall serve as the pharmacy's inventory until the next completed inventory as specified in Subsection (4) of this section; and
 - (d) when combining two pharmacies, each pharmacy shall:
 - (i) conduct a separate closing pharmacy inventory of controlled substances on the date of closure; and

- (ii) conduct a combined opening inventory of controlled substances for the new pharmacy prior to opening.
- (4) Requirement for annual controlled substances inventory shall be within 12 months following the inventory date of each year and may be taken within four days of the specified inventory date and shall include stocks including out-of-date drugs and drugs in automated pharmacy systems.
- (5) Requirements for change of ownership shall include the following:
 - (a) a pharmacy that changes ownership shall take an inventory of legend drugs and controlled substances including out-of-date drugs and drugs in automated pharmacy systems on the date of the change of ownership;
 - (b) such inventory shall constitute the closing inventory for the seller and the initial inventory for the buyer; and
 - (c) transfer of Schedule I and II controlled substances shall require the use of official DEA order form 222.
- (6) A pharmacy shall maintain a perpetual inventory of Schedule II controlled substances that shall be reconciled according to facility policy.

R156-17b-606. Operating Standards - Pharmacist Preceptor.

- (1) In accordance with Subsections 58-17b-601(1) and 58-17b-102(50), the operating standards for a pharmacist preceptor are established in this section.
- (2) A pharmacist preceptor shall:
 - (a) hold an active and good standing pharmacist license permitting practice in the jurisdiction where the pharmacist is acting as a preceptor;
 - (b) have engaged in active practice as a licensed pharmacist for at least one year immediately preceding the internship, in any jurisdiction; and
 - (c) ensure the totality of the internship circumstances are safe and appropriate according to generally recognized industry standards of practice;
- (3) A pharmacist preceptor may provide indirect, on-site supervision to:
 - (a) up to two pharmacy interns during a working shift, except as provided in Subsection (3)(b);
 - (b) up to five pharmacy interns at public-health outreach programs such as informational health fairs, chronic disease state screening and education programs, or immunization clinics.
- (4) A pharmacist preceptor shall document the number of internship hours completed by the pharmacy intern, and evaluate the quality of the pharmacy intern's performance during the internship.
- (5) A preceptor is responsible for the pharmacy intern's actions related to the practice of pharmacy while the pharmacy intern is practicing under the preceptor's supervision.

R156-17b-607. Operating Standards - Supportive Personnel.

- (1) In accordance with Subsection 58-17b-102(71)(a), supportive personnel may assist in any tasks not related to drug preparation or processing including:
 - (a) stock ordering and restocking;
 - (b) cashiering;
 - (c) billing;
 - (d) filing;
 - (e) receiving a written prescription and delivering it to the pharmacist, pharmacy intern, pharmacy technician, pharmacy technician trainee, DMP, or DMP designee;
 - (f) housekeeping; and
 - (g) delivering a pre-filled prescription to a patient.
- (2) Supportive personnel shall not enter information into a patient prescription profile or accept verbal refill information.
- (3) In accordance with Subsection 58-17b-102(71)(b) all supportive personnel shall be under the supervision of a licensed pharmacist or DMP. The licensed pharmacist or DMP shall be present in the area where the person being supervised is performing services and shall be immediately available to assist the person being supervised in the services being performed except for the delivery of pre-filled prescriptions as provided in Subsection (1)(g) above.
- (4) In accordance with Subsection 58-17b-601(1), a pharmacist, pharmacy intern, pharmacy technician, pharmacy technician trainee, DMP, or DMP designee whose license has been revoked or is suspended shall not be allowed to provide any support services in a pharmacy.

R156-17b-608. Common Carrier Delivery.

A pharmacy that employs the United States Postal Service or other common carrier to deliver a filled prescription directly to a patient shall, under the direction of the PIC, RDPIC, DMPIC, or other responsible employee:

- (1) use adequate storage or shipping containers and shipping processes to ensure drug stability and potency. The shipping processes shall include the use of appropriate packaging material and devices, according to the recommendations of the manufacturer or the United States Pharmacopeia Chapter 1079, in order to ensure that the drug is kept at appropriate storage temperatures throughout the delivery process to maintain the integrity of the medication;
- (2) use shipping containers that are sealed in a manner to detect evidence of opening or tampering;
- (3) develop and implement policies and procedures to ensure accountability, safe delivery, and compliance with temperature requirements. The policies and procedures shall address when drugs do not arrive at their destination in a timely manner or when there

is evidence that the integrity of a drug was compromised during shipment. In these instances, the pharmacy shall make provisions for the replacement of the drugs;

(4)(i) provide for an electronic, telephonic, or written communication mechanism for a pharmacy to offer counseling to the patient as defined in Section 58-17b-613; and

(ii) provide documentation of such counseling; and

(5) provide information to the patient indicating what the patient should do if the integrity of the packaging or drug was compromised during shipment.

R156-17b-609. Operating Standards - Medication Profile System.

In accordance with Subsections 58-17b-601(1) and 58-17b-604(1), the following operating standards shall apply with respect to medication profile systems:

(1) Patient profiles, once established, shall be maintained by a pharmacy dispensing to patients on a recurring basis for a minimum of one year from the date of the most recent prescription filled or refilled; except that a hospital pharmacy may delete the patient profile for an inpatient upon discharge if a record of prescriptions is maintained as a part of the hospital record.

(2) Information to be included in the profile shall be determined by a responsible pharmacist or DMP at the pharmaceutical facility but shall include as a minimum:

(a) full name of the patient, address, telephone number, date of birth or age and gender;

(b) patient history where significant, including known allergies and drug reactions, and a list of prescription drugs obtained by the patient at the pharmacy including:

(i) name of prescription drug;

(ii) strength of prescription drug;

(iii) quantity dispensed;

(iv) date of filling or refilling;

(v) charge for the prescription drug as dispensed to the patient; and

(c) any additional comments relevant to the patient's drug use.

(3) Patient medication profile information shall be recorded by a pharmacist, pharmacy intern, pharmacy technician, pharmacy technician trainee, or DMP designee.

R156-17b-610. Operating Standards - Patient Counseling.

In accordance with Subsection 58-17b-601(1), guidelines for providing patient counseling established in Section 58-17b-613 include the following:

(1)(a) Counseling shall be offered orally in person, unless the patient or patient's agent is not at the pharmacy or a specific communication barrier prohibits oral communication.

(b) Counseling may be provided through a telepharmacy system.

(2) A pharmacy facility shall orally offer to counsel, but is not required to counsel a patient or patient's agent who refuses such counseling.

(3) Based upon the professional judgment of the pharmacist, pharmacy intern, or DMP, patient counseling may include the following elements:

(a) the name and description of the prescription drug;

(b) the dosage form, dose, route of administration and duration of drug therapy;

(c) intended use of the drug, when known, and expected action;

(d) special directions and precautions for preparation, administration and use by the patient;

(e) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

(f) techniques for self-monitoring drug therapy;

(g) proper storage;

(h) prescription refill information;

(i) action to be taken in the event of a missed dose;

(j) pharmacist comments relevant to the individual's drug therapy, including any other information specific to the patient or drug; and

(k) the date after which the prescription should not be taken or used, or the beyond use date.

(4) The offer to counsel shall be documented. Documentation shall be maintained for a period of five years, and be available for inspection by the Division within 7-10 business days of the Division's request.

(5) Only a pharmacist, pharmacy intern, or DMP may orally provide counseling to a patient or patient's agent and answer questions concerning prescription drugs.

(6) If a prescription drug order is delivered to the patient or patient's agent or other designated location:

(a) the information specified in Subsection (3) shall be delivered with the dispensed prescription in writing;

(b) if prescriptions are routinely delivered outside the area covered by the pharmacy's local telephone service, the pharmacist shall place on the prescription container or on a separate sheet delivered with the prescription container, the telephone number of the pharmacy and the statement "Written information about this prescription has been provided for you. Please read this information before you take this medication. If you have questions concerning this prescription, a pharmacist is available during normal business hours to answer these questions."; and

(c) the written information provided in Subsection (6)(b) shall be in the form of patient information leaflets similar to USP-NF patient information monographs or equivalent information.

(7) Patient counseling is not required for patients of a hospital or institution where other licensed health care professionals are authorized to administer the patient's drugs.

(8) A pharmacist or pharmacy intern who dispenses a self-administered hormonal contraceptive shall obtain a completed Utah Hormonal Contraceptive Self-Screening Risk Assessment Questionnaire and provide written information and counseling as described in Section 26-62-106.

R156-17b-610.5. Dispensing in Emergency Department - Patient's Immediate Need.

In accordance with Section 58-17b-610.5, the guidelines for medical practitioners to dispense drugs to a patient in a hospital emergency department are established in this section.

(1) To meet a patient's immediate needs, the prescribing practitioner may provide up to a three-day emergency supply, which is properly labeled according to Subsection R156-17b-610.5(3).

(2) Notwithstanding Subsection R156-17b-610.5(1), the following may be provided:

(a) a seven day supply of sexually-transmitted infections (STI) prophylaxis;

(b) a Naloxone kit.

(3) Labeling of an emergency supply shall at a minimum include:

(a) prescribing practitioner's name, facility name and telephone number;

(b) patient's name;

(c) name of medication and strength;

(d) date given;

(e) instructions for use; and

(f) beyond use date.

(4) Records of controlled substances dispensed by the prescribing practitioner shall be provided to the appropriate pharmacy so that the applicable prescription data can be reported to the Utah Controlled Substance Database.

R156-17b-610.6. Hospital Pharmacy Dispensing Prescription Drugs to Patients at Discharge to Meet a Patient's Immediate Needs.

In accordance with Section 58-17b-610.6, the guidelines for a hospital pharmacy to dispense to an individual who is no longer a patient, on the day discharged from the hospital setting, are established in this section.

(1) The prescription drug shall be dispensed:

(a) during regular inpatient hospital pharmacy hours, by a pharmacist; or

(b) outside of regular inpatient hospital pharmacy hours, by the prescribing practitioner using an appropriately labeled pre-packaged drug.

(2) Labeling for a prescription under Section 58-17b-610.6 shall at a minimum include:

(a) prescribing practitioner's name, facility name, and telephone number;

(b) patient's name;

(c) name and strength of medication;

(d) date given;

(e) instructions for use; and

(f) beyond use date.

(3) Applicable data of controlled substances dispensed shall be reported to the Utah Controlled Substance Database.

R156-17b-610.7. Partial Filling of a Schedule II Controlled Substance Prescription.

In accordance with Section 58-17b-610.7, a pharmacy that partially fills a prescription for a Schedule II controlled substance shall specify by prescription number for each partial fill the:

(a) date;

(b) quantity supplied; and

(c) quantity remaining of the prescription partially filled.

R156-17b-611. Operating Standards - Drug Therapy Management.

(1) In accordance with Subsections 58-17b-102(17) and 58-17b-601(1), decisions involving drug therapy management shall be made in the best interest of the patient. Drug therapy management may include:

(a) implementing, modifying and managing drug therapy according to the terms of the Collaborative Pharmacy Practice Agreement;

(b) collecting and reviewing patient histories;

(c) obtaining and checking vital signs, including pulse, temperature, blood pressure and respiration;

(d) ordering and evaluating the results of laboratory tests directly applicable to the drug therapy, when performed in accordance with approved protocols applicable to the practice setting; and

(e) such other patient care services as may be allowed by rule.

(2) For the purpose of promoting therapeutic appropriateness, a pharmacist shall at the time of dispensing a prescription, or a prescription drug order, review the patient's medication record. Such review shall at a minimum identify clinically significant conditions, situations or items, such as:

- (a) inappropriate drug utilization;
- (b) therapeutic duplication;
- (c) drug-disease contraindications;
- (d) drug-drug interactions;
- (e) incorrect drug dosage or duration of drug treatment;
- (f) drug-allergy interactions; and
- (g) clinical abuse or misuse.

(3) Upon identifying any clinically significant conditions, situations or items listed in Subsection (2) above, the pharmacist shall take appropriate steps to avoid or resolve the problem including consultation with the prescribing practitioner.

R156-17b-612. Operating Standards - Prescriptions.

In accordance with Subsection 58-17b-601(1), the following shall apply to prescriptions:

(1) Prescription orders for controlled substances including prescription transfers shall be handled in accordance with 21 CFR 1306.25 (2021).

(2) A prescription issued by an authorized licensed practitioner, if verbally communicated by an agent of that practitioner upon that practitioner's specific instruction and authorization, may be accepted by a pharmacist, pharmacy intern, or DMP.

(3) A prescription issued by a licensed prescribing practitioner, if electronically communicated by an agent of that practitioner, upon that practitioner's specific instruction and authorization, may be accepted by a pharmacist, pharmacy intern, pharmacy technician, pharmacy technician trainee, DMP, or DMP designee.

(4) In accordance with Sections 58-17b-609 and 58-17b-611, prescription files, including refill information, shall be maintained for a minimum of five years and shall be immediately retrievable in written or electronic format.

(5) In accordance with Section 58-17b-604, prescriptions for legend drugs having a remaining authorization for refill may be transferred by the pharmacist, pharmacy intern, pharmacy technician, at the discretion of the pharmacist on duty, or DMP at the pharmacy holding the prescription to a pharmacist, pharmacy intern, pharmacy technician, or DMP at another pharmacy upon the authorization of the patient to whom the prescription was issued or electronically as authorized under Subsection R156-17b-613(9). The transferring pharmacist, pharmacy intern, or DMP and receiving pharmacist, pharmacy intern, or DMP shall act diligently to ensure that the total number of authorized refills is not exceeded. The following additional terms apply to such a transfer:

(a) the transfer shall be communicated directly between pharmacists, pharmacy interns, pharmacy technicians or DMPs or as authorized under Subsection R156-17b-613(9);

(b) both the original and the transferred prescription drug orders shall be maintained for a period of five years from the date of the last refill;

(c) the pharmacist, pharmacy intern, or DMP transferring the prescription drug order shall void the prescription electronically or write void or transfer on the face of the invalidated prescription manually;

(d) the pharmacist, pharmacy intern, or DMP receiving the transferred prescription drug order shall:

(i) indicate on the prescription record that the prescription was transferred electronically or manually; and

(ii) record on the transferred prescription drug order the following information:

(A) original date of issuance and date of dispensing or receipt, if different from date of issuance;

(B) original prescription number and the number of refills authorized on the original prescription drug order;

(C) number of valid refills remaining and the date of last refill, if applicable;

(D) the name and address of the pharmacy and the name of the pharmacist, pharmacy intern, pharmacy technician, or DMP to whom such prescription is transferred; and

(E) the name of the pharmacist, pharmacy intern, or DMP transferring the prescription drug order information;

(e) the data processing system shall have a mechanism to prohibit the transfer or refilling of legend drugs or controlled substance prescription drug orders that have been previously transferred; and

(f) a pharmacist, pharmacy intern, pharmacy technician, or DMP may not refuse to transfer original prescription information to another pharmacist, pharmacy intern, pharmacy technician, or DMP who is acting on behalf of a patient and who is making a request for this information as specified in Subsection (12) of this section.

(6) Prescriptions for terminal patients in licensed hospices, home health agencies or nursing homes may be partially filled if the patient has a medical diagnosis documenting a terminal illness and may not need the full prescription amount.

(7) Refills may be dispensed only in accordance with the prescriber's authorization as indicated on the original prescription drug order.

(8) If there are no refill instructions on the original prescription drug order, or if refills authorized on the original prescription drug order have been dispensed, authorization from the prescribing practitioner shall be obtained prior to dispensing any refills.

(9) Refills of prescription drug orders for legend drugs may not be refilled after one year from the date of issuance of the original prescription drug order without obtaining authorization from the prescribing practitioner prior to dispensing any additional quantities of the drug.

(10) Refills of prescription drug orders for controlled substances shall be done in accordance with Subsection 58-37-6(7)(f).

(11) A pharmacist or DMP may exercise professional judgment in refilling a prescription drug order for a drug, other than a Schedule II controlled substance, without the authorization of the prescribing practitioner, if:

(a) the quantity of prescription drug dispensed does not exceed a 72-hour supply, unless the packaging is in a great quantity;

(b) failure to refill the prescription might result in an interruption of a therapeutic regimen or create patient suffering;

(c) either:

(i) a natural or manmade disaster has occurred that prohibits the pharmacist or DMP from being able to contact the practitioner; or

(ii) the pharmacist or DMP is unable to contact the practitioner after a reasonable effort, with the effort documented and the documentation available to the Division upon request;

(d) if the prescription was originally filled at another pharmacy:

(i) the patient has the prescription container label, receipt, or other documentation from the other pharmacy that contains the essential information; and

(ii) after a reasonable effort, the pharmacist or DMP is unable to contact the other pharmacy to transfer the remaining prescription refills or there are no refills remaining on the prescription; and

(e) the pharmacist or DMP:

(i) informs the patient or patient's agent at the time of dispensing that the refill is being provided without practitioner authorization, and that authorization is required for future refills;

(ii) informs the practitioner of the emergency refill at the earliest reasonable time;

(iii) maintains a record of the emergency refill containing the information required to be maintained on a prescription as specified in this subsection; and

(iv) affixes a label to the dispensing container as specified in Section 58-17b-602.

(12) The address specified in Subsection 58-17b-602(1)(b) shall be a physical address, not a post office box.

(13) In accordance with Subsection 58-37-6(7)(e), a prescription may not be written, issued, filled, or dispensed for a Schedule I controlled substance unless:

(a) the person who writes the prescription is licensed to prescribe Schedule I controlled substances; and

(b) the prescribed controlled substance is to be used in research.

(14) A pharmacist or pharmacy intern may dispense an emergency refill prescription for a drug a patient is currently using and on file with the pharmacy, other than a controlled substance, without the prescribing practitioner's authorization if they are not available promptly, in accordance with Section 58-17b-608, for:

(a) a 30 day supply with the prescribing practitioners instructions; or

(b) the quantity last dispensed at the pharmacy pursuant to the prescription as either a fill or a refill.

R156-17b-612a. Operating Standards - Prescription Devices.

(1) In accordance with Subsections 58-17b-601(1) and 58-17b-610.8, the operating standards for prescription devices are established in this section.

(2) The prescribing practitioner identified on the prescription document under Subsection 58-17-610.8(1) is the prescriber for the prescription device described in Subsection 58-17b-610.8(3).

(3) The pharmacist or pharmacy intern dispensing the prescription device shall determine the following:

(a) an appropriate dispense quantity;

(b) directions for device use; and

(c) refill.

(4) Each prescription device dispensed by a pharmacist or pharmacy intern shall be:

(a) dispensed in accordance with Subsection 58-17b-602(1)(a) through (e) and Section 58-17b-609; and

(b) dispensed from a Class A or Class B pharmacy.

(5)(a) Notice of the prescription device dispense shall be conveyed to the prescribing practitioner in writing, by electronic transmission, or by telephone within five business days following the prescription device dispense.

(b) The prescription device dispense notice shall include the following:

(i) pharmacy name;

(ii) pharmacy phone number;

(iii) patient;

(iv) dispensed quantity;

(v) directions for use; and

(vi) refill.

R156-17b-612b. Operating Standards - Exhausted Prescription for Insulin.

(1) In accordance with Subsections 58-17b-601(1) and 58-17b-608.2(7), the operating standards for dispensing an exhausted prescription for insulin are established in this section.

(2) Under Subsection 58-17b-608.2(3), a refill for an exhausted prescription in an amount up to a supply for 60 days may be for the nearest available package size.

- (3) The pharmacist who dispenses a refill of an exhausted prescription of insulin shall obtain:
 - (a) the prescribing information for the insulin;
 - (b) prescription directions; and
 - (c) other documentation based on the pharmacist's clinical judgment.
- (4) The pharmacist shall document the following on the exhausted prescription refill hard copy or in the medication profile system:
 - (a) the information described in Subsection (3);
 - (b) the method of the attempt under Subsection 58-1b7-608.2(5)(a) to contact the patient's prescribing practitioner; and
 - (c) the method of the notification to the patient under Subsection 58-17b-608.2(5)(b) regarding the outcome of the attempt to contact the prescribing practitioner.
- (5) An exhausted prescription refill label shall state "exhausted prescription".

R156-17b-613. Operating Standards - Issuing Prescription Orders by Electronic Means.

In accordance with Rules R156-1 and R156-37, and Subsections 58-17b-102(29), 58-17b-102(30), 58-17b-602(1), prescription orders may be issued by electronic means of communication according to the following standards:

- (1) Prescription orders for Schedule II - V controlled substances received by electronic communication shall be handled according to 21 CFR 1304.06 (2021).
- (2) Prescription orders for non-controlled substances received by electronic communication may be dispensed by a pharmacist, pharmacy intern, or DMP only if the following conditions are satisfied:
 - (a) Electronically transmitted prescription orders shall include the following:
 - (i) information that is required to be contained in a prescription order pursuant to Section 58-17b-602;
 - (ii) the time and date of the transmission, and if a facsimile transmission, the electronically encoded date, time, and fax number of the sender; and
 - (iii) the name of the pharmacy intended to receive the transmission.
 - (b) A prescription order shall be transmitted under the direct supervision of the prescribing practitioner or the prescribing practitioner's designated agent.
 - (c) The pharmacist or DMP shall exercise professional judgment regarding the accuracy and authenticity of the transmitted prescription.
 - (d) A practitioner or the practitioner's agent shall provide voice verification when requested by the pharmacist receiving a medication order.
 - (e) The pharmacist, pharmacy intern, pharmacy technician at the discretion of the pharmacist on duty, or DMP shall assure that each electronically transferred prescription order is valid and shall authenticate a prescription order issued by a prescribing practitioner that has been transmitted to the dispensing pharmacy before filling it, whenever there is a question.
 - (f)(i) A practitioner may authorize an agent to electronically transmit a prescription if the agent's identifying information is on the transmission.
 - (ii) The practitioner's electronic signature, or other secure method of validation, shall be provided with the electronic prescription.
- (3) an electronically transmitted prescription order that meets the requirements of Subsection (2) shall be the original prescription.
- (4) This section does not apply to the use of electronic equipment to transmit prescription orders within inpatient medical facilities.
- (5) An agreement between a prescribing practitioner and a pharmacy may not require that prescription orders be transmitted by electronic means from the prescribing practitioner only to that pharmacy.
- (6) The pharmacist or DMP shall retain a printed copy of an electronic prescription, or a record of an electronic prescription that is readily retrievable and printable, for a minimum of five years. The printed copy shall be of non-fading legibility.
- (7) Wholesalers, distributors, manufacturers, pharmacists, and pharmacies may not supply electronic equipment to a prescriber for transmitting prescription orders.
- (8) An electronically transmitted prescription order shall be transmitted to the pharmacy of the patient's choice.
- (9) Prescription orders electronically transmitted to the pharmacy by the patient may not be filled or dispensed.
- (10) A prescription order for a legend drug or controlled substance in Schedule III through V may be transferred up to the maximum refills permitted in accordance with 21 CFR 1306.22 (2021) or by the prescriber by electronic transmission, if:
 - (a) the pharmacies share a real-time, online database;
 - (b) the information required to be on the transferred prescription has the same information described in Subsection R156-17b-612(5)(a) through (f); and
 - (c) pharmacists, pharmacy interns, pharmacy technicians, or pharmacy technician trainees, DMPs, and DMP designees electronically accessing the same prescription drug order records may electronically transfer prescription information if the data processing system has a mechanism to send a message to the transferring pharmacy containing the following information:
 - (i) the fact that the prescription drug order was transferred;
 - (ii) the unique identification number of the prescription drug order transferred;
 - (iii) the name of the pharmacy to which it was transferred; and
 - (iv) the date and time of the transfer.

R156-17b-614a. Operating Standards - Class A or Class B Pharmacy - General Operating Standards.

In accordance with Subsection 58-17b-601(1), the following operating standards apply to Class A and Class B pharmacies, and may be supplemented or amended by additional standards in this rule applicable to specific types of Class A and B pharmacies.

- (1) The general operating standards include:
 - (a) A facility shall be well lighted, well ventilated, clean and sanitary.
 - (b) A facility that transfers a drug from a manufacturer's or distributor's original container to another container shall have a sink with hot and cold culinary water separate and apart from restroom facilities. This sink requirement does not apply to clean rooms where sterile products are prepared. Clean rooms may not have sinks or floor drains.
 - (c) Required equipment shall be clean and in good operating condition.
 - (d) A facility shall be equipped to store prescription drugs and durable medical equipment:
 - (i) in an orderly manner that permits clear identification, separation, and easy retrieval of products; and
 - (ii) in an environment necessary to maintain the integrity of the product inventory.
 - (e) A facility shall be equipped to permit practice within the standards and ethics of the profession as dictated by the usual and ordinary scope of practice conducted within that facility.
 - (f) A facility shall be stocked with the quality and quantity of product necessary for the facility to meet its scope of practice in a manner consistent with the public safety.
 - (g) A facility that dispenses controlled substances shall be equipped with a security system that:
 - (i) permits detection of entry at all times when the facility is closed; and
 - (ii) provides notice of unauthorized entry to an individual.
 - (h) A pharmacy department shall:
 - (i) be equipped with a lock where drugs are stored; and
 - (ii) be securely locked when the pharmacy department is closed.
 - (i) A facility shall have a counseling area to allow for confidential patient counseling, if applicable.
- (2)(a) Prescription labels for compounded sterile and non-sterile medications, when dispensed to the patient or patient's agent, shall include:

- (i) the minimum information required under Section 58-17b-602;
 - (ii) generic name;
 - (iii) quantity or concentration of each active ingredient; and
 - (iv) labeling for sterile preparation for parenteral use shall include:
 - (A) the name of the diluent;
 - (B) assigned compounding record or lot number; and
 - (C) the phrase "compounded preparation."
- (b) The requirements described in Subsections (2)(a)(i) and (2)(a)(iv) shall not apply to a label on the container of a drug that a health care provider administers to a patient at:
 - (i) a pharmaceutical administration facility; or
 - (ii) a hospital licensed under Title 26, Chapter 21, Health Care Facility Licensing and Inspection Act.
- (3) The temperature of the pharmacy shall be maintained within a range compatible with the proper storage of drugs.

If a refrigerator or freezer is necessary to properly store drugs at the pharmacy, the pharmacy shall keep a daily written or electronic log of the temperature of the refrigerator or freezer on days of operation. The pharmacy shall retain each log entry for at least three years.

- (4) A facility shall have current editions of the following reference publications in print or electronic format, that are readily available to and retrievable by facility personnel:

- (a) Title 58, Chapter 1, Division of Occupational and Professional Licensing Act;
 - (b) Rule R156-1, General Rule of the Division of Occupational and Professional Licensing;
 - (c) Title 58, Chapter 17b, Pharmacy Practice Act;
 - (d) Rule R156-17b, Utah Pharmacy Practice Act Rule;
 - (e) Title 58, Chapter 37, Utah Controlled Substances Act;
 - (f) Rule R156-37, Utah Controlled Substances Act Rule;
 - (g) Title 58, Chapter 37f, Controlled Substance Database Act;
 - (h) R156-37f, Controlled Substance Database Act Rule;
 - (i) 21 CFR 1300 et seq. (2021) or equivalent such as the USP DI Drug Reference Guides;
 - (j) current FDA-Approved Drug Products; and
 - (k) any other general drug references necessary to permit practice, as dictated by the usual and ordinary scope of practice conducted within that facility.

- (5)(a) A facility shall maintain a current list of licensed employees involved in the practice of pharmacy at the facility, that includes:

- (i) individual licensee names;
 - (ii) license classifications;
 - (iii) license numbers; and
 - (iv) license expiration dates.

(b) The list shall be readily retrievable for inspection by the Division, and may be maintained in paper or electronic form.

(6) A pharmacy may not dispense a prescription drug or device to a patient unless a pharmacist or DMP is physically present and immediately available in the facility, or, for a remote dispensing pharmacy, physically present and immediately available in the facility or supervising through a telepharmacy system.

(7) Only a licensed Utah pharmacist, DMP, or authorized personnel shall have access to the pharmacy when the pharmacy is closed.

(8) The facility or parent company shall maintain a record for at least five years of the initials or identification codes that identify each dispensing pharmacist or DMP by name. The initials or identification code shall be unique to ensure that each pharmacist or DMP can be identified; therefore identical initials or identification codes may not be used.

(9) The pharmacy facility shall maintain:

(a) copy 3 of DEA order form 222 that has been properly dated, initialed, and filed;

(b) copies of each unaccepted or defective order form; and

(c) any attached statements or other documents.

(10) If applicable, a hard copy of a power of attorney authorizing a pharmacist, DMP, or DMP designee to sign DEA order form 222 shall be available to the Division upon request.

(11) A pharmacist, DMP, or other responsible individual shall verify that controlled substances are listed on the suppliers' invoices and were actually received, by clearly recording their initials and the actual date of receipt of the controlled substances.

(12) The facility shall maintain a record of suppliers' credit memos for controlled substances.

(13) A copy of the inventories required under Section R156-17b-605 shall be made available to the Division when requested.

(14) The facility shall maintain hard copy reports of surrender or destruction of controlled substances and legend drugs submitted to appropriate state or federal agencies.

(15) If the pharmacy does not store drugs in a locked cabinet and has a drop or false ceiling, the pharmacy's perimeter walls shall extend to the hard deck, or the pharmacy shall take other measures to prevent unauthorized entry into the pharmacy.

R156-17b-614b. Operating Standards - Class B pharmacy designated as a Branch Pharmacy.

In accordance with Subsections 58-17b-102(8) and 58-1-301(3), the qualifications for designation as a branch pharmacy include the following:

(1) The Division, in collaboration with the Board, shall approve the location of each branch pharmacy. The following shall be considered in granting such designation:

(a) the distance between or from nearby alternative pharmacies and all other factors affecting access of persons in the area to alternative pharmacy resources;

(b) the availability at the location of qualified persons to staff the pharmacy, including the physician, physician assistant or advanced practice registered nurse;

(c) the availability and willingness of a parent pharmacy and supervising pharmacist to assume responsibility for the branch pharmacy;

(d) the availability of satisfactory physical facilities in which the branch pharmacy may operate; and

(e) the totality of conditions and circumstances which surround the request for designation.

(2) A branch pharmacy shall be licensed as a pharmacy branch of an existing Class A or B pharmacy licensed by the Division.

(3) The application for designation of a branch pharmacy shall be submitted by the licensed parent pharmacy seeking such designation. In the event that more than one licensed pharmacy makes application for designation of a branch pharmacy location at a previously undesignated location, the Division in collaboration with the Board shall review all applications for designation of the branch pharmacy and, if the location is approved, shall approve for licensure the applicant determined best able to serve the public interest as identified in Subsection (1).

(4) The application shall include the following:

(a) complete identifying information concerning the applying parent pharmacy;

(b) complete identifying information concerning the designated supervising pharmacist employed at the parent pharmacy;

(c) address and description of the facility in which the branch pharmacy is to be located;

(d) specific formulary to be stocked indicating with respect to each prescription drug, the name, the dosage strength and dosage units in which the drug will be prepackaged;

(e) complete identifying information concerning each person located at the branch pharmacy who will dispense prescription drugs in accordance with the approved protocol; and

(f) protocols under which the branch pharmacy will operate and its relationship with the parent pharmacy to include the following:

(i) the conditions under which prescription drugs will be stored, used and accounted for;

(ii) the method by which the drugs will be transported from parent pharmacy to the branch pharmacy and accounted for by the branch pharmacy; and

(iii) a description of how records will be kept with respect to:

(A) formulary;

(B) changes in formulary;

- (C) record of drugs sent by the parent pharmacy;
- (D) record of drugs received by the branch pharmacy;
- (E) record of drugs dispensed;
- (F) periodic inventories; and
- (G) any other record contributing to an effective audit trail with respect to prescription drugs provided to the branch pharmacy.

R156-17b-614c. Operating Standards - Class B - Pharmaceutical Administration Facility.

In accordance with Subsections 58-17b-102(44) and 58-17b-601(1), the following operating standards apply to prescription drugs that are held, stored, or otherwise under the control of a pharmaceutical administration facility for administration to patients:

(1) The licensed consulting pharmacist shall provide consultation on each aspect of pharmacy services in the facility; establish a system of records of receipt and disposition of controlled substances in sufficient detail to enable an accurate reconciliation; and determine that drug records are in order and that an account of all controlled substances is maintained and periodically reconciled.

(2) Authorized destruction of prescription drugs shall be witnessed by the medical or nursing director or a designated physician, registered nurse or other licensed person employed in the facility and the consulting pharmacist or licensed pharmacy technician, and shall be in compliance with 21 CFR 1317 (2021).

(3) Prescriptions for patients in the facility may be verbally requested by a licensed prescribing practitioner and may be entered as the prescribing practitioner's order; but the practitioner must personally sign the order in the facility record within 72 hours if a Schedule II controlled substance and within 30 days if any other prescription drug. The prescribing practitioner's verbal order may be copied and forwarded to a pharmacy for dispensing and may serve as the pharmacy's record of the prescription order.

(4) Prescriptions for controlled substances for patients in Class B pharmaceutical administration facilities shall be dispensed according to Title 58, Chapter 37, Utah Controlled Substances Act, and Rule R156-37, Utah Controlled Substances Act Rules.

(5) Requirements for emergency drug kits shall include:

(a) an emergency drug kit may be used by pharmaceutical administration facilities. The emergency drug kit shall be considered to be a physical extension of the pharmacy supplying the emergency drug kit and shall remain under the ownership of that pharmacy;

(b) the contents and quantity of drugs and supplies in the emergency drug kit shall be determined by the Medical Director or Director of Nursing of the pharmaceutical administration facility and the consulting pharmacist of the supplying pharmacy;

(c) a copy of the approved list of contents shall be conspicuously posted on or near the kit;

(d) the emergency kit shall be used only for bona fide emergencies and only when medications cannot be obtained from a pharmacy in a timely manner;

(e) records documenting the receipt and removal of drugs in the emergency kit shall be maintained by the facility and the pharmacy;

(f) the pharmacy shall be responsible for ensuring proper storage, security and accountability of the emergency kit and shall ensure that:

(i) the emergency kit is stored in a locked area and is locked itself; and

(ii) emergency kit drugs are accessible only to licensed physicians, physician assistants and nurses employed by the facility;

(g) the contents of the emergency kit, the approved list of contents and related records shall be made freely available and open for inspection to appropriate representatives of the Division and the Utah Department of Health.

R156-17b-614d. Operating Standards - Class B - Nuclear Pharmacy.

(1) In accordance with Subsection 58-17b-601(1), the operating standards for a Class B pharmacy designated as a nuclear pharmacy are established in this section.

(2) A nuclear pharmacy shall have the following:

(a) have applied for or possess a current Utah Radioactive Materials License; and

(b) adequate space and equipment commensurate with the scope of services required and provided.

(3) Nuclear pharmacies shall only dispense radiopharmaceuticals that comply with acceptable standards of quality assurance.

(4) Nuclear pharmacies shall maintain a library commensurate with the level of radiopharmaceutical service to be provided.

(5)(a) A licensed Utah pharmacist shall be immediately available on the premises at any time when the facility is open or available to engage in the practice of pharmacy.

(b) In addition to Utah licensure, the pharmacist shall have classroom and laboratory training and experience as required by the Utah Radiation Control Rules.

(6) This rule does not prohibit:

(a) a licensed pharmacy intern or technician from acting under the direct supervision of a pharmacist preceptor who meets the requirements to supervise a nuclear pharmacy; or

- (b) a Utah Radioactive Materials license from possessing and using radiopharmaceuticals for medical use.
- (7) A hospital nuclear medicine department or an office of a physician-surgeon, osteopathic physician-surgeon, veterinarian, podiatric physician or dentist that has a current Utah Radioactive Materials License does not require licensure as a Class B pharmacy.
- (8) A nuclear pharmacy preparing sterile compounds shall follow the USP-NF Chapter 797 Compound for sterile preparations.
- (9) A nuclear pharmacy preparing medications for a specific person shall be licensed as a Class B - nuclear pharmacy if located in Utah, and as a Class D pharmacy if located outside of Utah.

R156-17b-614e. Operating Standards - Compounding.

- (1) A person engaging in sterile or nonsterile compounding shall practice in accordance with all applicable federal and state laws and rules, and in accordance with the USP-NF, including:
 - (a) USP General Chapter <797> Pharmaceutical Compounding - Sterile Preparations;
 - (b) USP General Chapter <795> Pharmaceutical Compounding - Nonsterile Preparations; and
 - (c) USP General Chapter <825> Radiopharmaceuticals - Preparation, Compounding, Dispensing, and Repackaging.
- (2) These operating standards shall apply:
 - (a) to any person licensed under Title 58, Chapter 17b, Pharmacy Practice Act, that engages in compounding; and
 - (b) to the compounding of all sterile or nonsterile compounded pharmaceuticals, antineoplastic drugs, or non-antineoplastic drugs, no matter where the patient is located.

R156-17b-614f. Operating Standards - Central Prescription Processing.

In accordance with Subsection 58-17b-601(1), the following operating standards apply to pharmacies that engage in central prescription processing as defined in Subsection 58-17b-102(9):

- (1) Centralized prescription processing services may be performed if the parties:
 - (a) have common ownership or common administrative control; or
 - (b) have a written contract outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of said contract; and
 - (c) share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to fill or refill a prescription drug order.
- (2) The parties performing or contracting for centralized prescription processing services shall maintain a policy and procedures manual, and documentation of implementation, which shall be made available to the Division upon inspection and which includes the following:
 - (a) a description of how the parties will comply with federal and state laws and regulations;
 - (b) appropriate records to identify the responsible pharmacists and the dispensing and counseling process;
 - (c) a mechanism for tracking the prescription drug order during each step in the dispensing process;
 - (d) a description of adequate security to protect the integrity and prevent the illegal use or disclosure of protected health information; and
 - (e) a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems.
- (3) "Non drug or device handling central prescription processing pharmacies", as defined in Subsection R156-17b-102(40), shall be licensed as Class E pharmacies. All other central prescription processing pharmacies shall be licensed in the appropriate pharmacy license classification.

R156-17b-614g. Operating Standards - Class A or Class B Pharmacy - Remote Dispensing Pharmacy.

- (1) In accordance with Subsections 58-17b-102(58), 58-17b-601(1), 58-17b-612(1)(b), and 58-1-301(3), the operating standards for a remote dispensing pharmacy are established in this section.
- (2) A remote dispensing pharmacy shall:
 - (a) be a Class A or Class B pharmacy;
 - (b) have a Class A or Class B pharmacy serve as its supervising pharmacy to oversee its operations; and
 - (c) be located in an area of need as defined in Subsection R156-17b-102(4).
- (3) A remote dispensing pharmacy may not perform compounding.
- (4)(a) The supervising pharmacy's PIC shall serve as the remote dispensing pharmacy's RDPIC, who is responsible for any remote dispensing pharmacy operations.
- (b) An RDPIC may not serve as the RDPIC for more than one remote dispensing pharmacy, unless approved by the Division in collaboration with the Board.
- (5) (a) At any time that a remote dispensing pharmacy is open and available to serve patients, its pharmacy technicians shall be physically or electronically supervised by a pharmacist from the supervising pharmacy, under Subsection 58-17b-102(70).
- (b) In accordance with Subsections 58-17b-612(1)(b) and (d) a pharmacist may oversee the operation of up to two remote dispensing pharmacies simultaneously.
- (c) Unless a pharmacist is physically present, a remote dispensing pharmacy shall be staffed by no more than two licensed pharmacy technicians.

(d) Each pharmacy technician staffing a remote dispensing pharmacy shall have at least 500 hours of pharmacy technician experience.

(e)(i) Adequate supervision by a pharmacist of a remote dispensing pharmacy shall include maintaining uninterrupted visual supervision and auditory communication with the site, and full supervisory control of the automated system, if applicable.

(ii) A supervising pharmacist may not delegate supervision to any other person.

(6) The supervising pharmacy shall maintain a surveillance system and telepharmacy system that provides for effective video and audio communication between supervising pharmacy personnel and remote dispensing pharmacy personnel and patients, that includes the following features:

(a) provides an adequate number of views of the entire site;

(b) facilitates adequate pharmacist supervision;

(c) allows the appropriate exchanges of visual, verbal, and written communication for patient counseling and other matters involved in the lawful transaction or dispensing of drugs;

(d) confirms that the drug selected to fill the prescription is the same as indicated on the prescription label and prescription; and

(e) is secure and HIPAA compliant as defined in R156-17b-102(64).

(7)(a) Each component of the telepharmacy system shall be in good working order.

(b) If a component of the system is malfunctioning, the remote dispensing pharmacy shall immediately close to the public and remain closed until system corrections or repairs are completed, unless a pharmacist is present onsite.

(8)(a) The supervising pharmacy shall develop and include in both the supervising pharmacy's and the remote dispensing pharmacy's policies and procedures a plan for continuation of pharmaceutical services by the remote dispensing pharmacy in case of an emergency interruption.

(b)(i) The plan shall address the timely arrival at the remote dispensing pharmacy of necessary personnel, and the delivery to the remote dispensing pharmacy of necessary supplies, within a reasonable period of time following the identification of an emergency need.

(ii) A pharmacist shall be available onsite at the remote dispensing pharmacy as soon as possible after an emergency, and shall notify the Division in writing if the time exceeds 24 hours.

(c) The plan may provide for alternate methods of continuation of the services of the remote dispensing pharmacy, including personal delivery of patient prescription medications from an alternate pharmacy location or on-site pharmacist staffing at the remote dispensing pharmacy.

(9)(a)(i) The remote dispensing pharmacy's security system shall track entries into the remote dispensing pharmacy.

(ii) The RDPIC shall periodically review the record of entries.

(b) A remote dispensing pharmacy shall display a sign easily visible to the public that informs patients of the following:

(i) that the pharmacy is a remote dispensing pharmacy;

(ii) the location of the supervising pharmacy; and

(iii) that at the patient's request a pharmacist will counsel the patient using audio and video communication systems.

(10)(a)(i) The supervising pharmacy shall maintain records of the orders entered into its information system, including orders entered from the remote dispensing pharmacy.

(ii) Electronic records shall be available to and accessible from both the remote dispensing pharmacy and the supervising pharmacy.

(iii) The original records of the controlled substance prescriptions dispensed from the remote dispensing pharmacy shall be maintained at the remote dispensing pharmacy.

(b) The remote dispensing pharmacy shall retain a recording of surveillance, excluding patient communications, for at least 45 days.

(c)(i) The RDPIC shall oversee documented monthly inspections of the remote dispensing pharmacy.

(ii) Documentation of the inspections shall be kept for five years, and shall include:

(A) maintenance and reconciliation of any controlled substance;

(B) a perpetual inventory of Schedule II controlled substances;

(C) temperature logs of the refrigerator and freezer that hold medications; and

(D) the RDPIC's periodic review of the record of entries into the remote dispensing pharmacy.

R156-17b-615. Operating Standards - Class C Pharmacy - Pharmaceutical Wholesaler/Distributor and Pharmaceutical Manufacturer.

In accordance with Subsections 58-17b-102(47) and 58-17b-601(1), the operating standards for Class C pharmacies designated as pharmaceutical wholesaler/distributor and pharmaceutical manufacturer licensees includes the following:

(1) Each pharmaceutical wholesaler or manufacturer that distributes or manufactures drugs or medical devices in Utah shall be licensed by the Division. A separate license shall be obtained for each separate location engaged in the distribution or manufacturing of prescription drugs. Business names cannot be identical to the name used by another unrelated wholesaler licensed to purchase drugs and devices in Utah.

(2) Manufacturers distributing only their own FDA-approved:

(a) prescription drugs or prescription drugs that are co-licensed products satisfy the requirement in Subsection (1) by registering their establishment with the FDA pursuant to 21 CFR Part 207 and submitting the information required by 21 CFR Part 205 including any amendments thereto, to the Division; or

(b) devices or devices that are co-licensed products, including products packaged with devices, such as convenience kits, that are exempt from the definition of transaction in 21 USC sec. 360eee (24)(B)(xii-xvi) satisfy the requirement in Subsection (1) by registering their establishment with the FDA pursuant to 21 CFR.

(3) An applicant for licensure as a pharmaceutical wholesale distributor shall provide the following minimum information:

(a) All trade or business names used by the licensee (including "doing business as" and "formerly known as");

(b) Name of the owner and operator of the license as follows:

(i) if a person, the name, business address, social security number and date of birth;

(ii) if a partnership, the name, business address, and social security number and date of birth of each partner, and the partnership's federal employer identification number;

(iii) if a corporation, the name, business address, social security number and date of birth, and title of each corporate officer and director, the corporate names, the name of the state of incorporation, federal employer identification number, and the name of the parent company, if any, but if a publicly traded corporation, the social security number and date of birth for each corporate officer shall not be required;

(iv) if a sole proprietorship, the full name, business address, social security number and date of birth of the sole proprietor and the name and federal employer identification number of the business entity;

(v) if a limited liability company, the name of each member, social security number of each member, the name of each manager, the name of the limited liability company and federal employer identification number, and the name of the state where the limited liability company was organized; and

(c) any other relevant information required by the Division.

(4) The licensed facility need not be under the supervision of a licensed pharmacist, but shall be under the supervision of a designated representative who meets the following criteria:

(a) is at least 21 years of age;

(b) has been employed full time for at least three years in a pharmacy or with a pharmaceutical wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to prescription drugs;

(c) is employed by the applicant full time in a managerial level position;

(d) is actively involved in and aware of the actual daily operation of the pharmaceutical wholesale distribution;

(e) is physically present at the facility during regular business hours, except when the absence of the designated representative is authorized, including but not limited to, sick leave and vacation leave; and

(f) is serving in the capacity of a designated representative for only one licensee at a time.

(5) The licensee shall provide the name, business address, and telephone number of a person to serve as the designated representative for each facility of the pharmaceutical wholesaler that engages in the distribution of drugs or devices.

(6) All pharmaceutical wholesalers and manufacturer shall publicly display or have readily available all licenses and the most recent inspection report administered by the Division.

(7) All Class C pharmacies shall:

(a) be of suitable size and construction to facilitate cleaning, maintenance and proper operations;

(b) have storage areas designed to provide adequate lighting, ventilation, sanitation, space, equipment and security conditions;

(c) have the ability to control temperature and humidity within tolerances required by all prescription drugs and prescription drug precursors handled or used in the distribution or manufacturing activities of the applicant or licensee;

(d) provide for a quarantine area for storage of prescription drugs and prescription drug precursors that are outdated, damaged, deteriorated, misbranded, adulterated, opened or unsealed containers that have once been appropriately sealed or closed or in any other way unsuitable for use or entry into distribution or manufacturing;

(e) be maintained in a clean and orderly condition; and

(f) be free from infestation by insects, rodents, birds or vermin of any kind.

(8) Each facility used for wholesale drug distribution or manufacturing of prescription drugs shall:

(a) be secure from unauthorized entry;

(b) limit access from the outside to a minimum in conformance with local building codes, life and safety codes and control access to persons to ensure unauthorized entry is not made;

(c) limit entry into areas where prescription drugs, prescription drug precursors, or prescription drug devices are held to authorized persons who have a need to be in those areas;

(d) be well lighted on the outside perimeter;

(e) be equipped with an alarm system to permit detection of entry and notification of appropriate authorities at all times when the facility is not occupied for the purpose of engaging in distribution or manufacturing of prescription drugs; and

(f) be equipped with security measures, systems and procedures necessary to provide reasonable security against theft and diversion of prescription drugs or alteration or tampering with computers and records pertaining to prescription drugs or prescription drug precursors.

(9) Each facility shall provide the storage of prescription drugs, prescription drug precursors, and prescription drug devices in accordance with the following:

(a) all prescription drugs and prescription drug precursors shall be stored at appropriate temperature, humidity and other conditions in accordance with labeling of such prescription drugs or prescription drug precursors or with requirements in the USP-NF;

(b) if no storage requirements are established for a specific prescription drug, prescription drug precursor, or prescription drug devices, the products shall be held in a condition of controlled temperature and humidity as defined in the USP-NF to ensure that its identity, strength, quality and purity are not adversely affected; and

(c) there shall be established a system of manual, electromechanical or electronic recording of temperature and humidity in the areas in which prescription drugs, prescription drug precursors, and prescription drug devices are held to permit review of the record and ensure that the products have not been subjected to conditions that are outside of established limits.

(10) Each person who is engaged in pharmaceutical wholesale distribution of prescription drugs for human use that leave, or have ever left, the normal distribution channel shall, before each pharmaceutical wholesale distribution of such drug, provide a pedigree to the person who receives such drug. A retail pharmacy or pharmacy warehouse shall comply with the requirements of this section only if the pharmacy engages in pharmaceutical wholesale distribution of prescription drugs. The pedigree shall:

(a) include all necessary identifying information concerning each sale in the chain of distribution of the product from the manufacturer, through acquisition and sale by any pharmaceutical wholesaler, until sale to a pharmacy or other person dispensing or administering the prescription drug. At a minimum, the necessary chain of distribution information shall include:

(i) name, address, telephone number, and if available, the email address of each owner of the prescription drug, and each pharmaceutical wholesaler of the prescription drug;

(ii) name and address of each location from which the product was shipped, if different from the owner's;

(iii) transaction dates;

(iv) name of the prescription drug;

(v) dosage form and strength of the prescription drug;

(vi) size of the container;

(vii) number of containers;

(viii) lot number of the prescription drug;

(ix) name of the manufacturer of the finished dose form; and

(x) National Drug Code (NDC) number.

(b) be maintained by the purchaser and the pharmaceutical wholesaler for five years from the date of sale or transfer and be available for inspection or use upon a request of an authorized officer of the law.

(11) Each facility shall comply with the following requirements:

(a) in general, each person who is engaged in pharmaceutical wholesale distribution of prescription drugs shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of the prescription drugs. These records shall include pedigrees for all prescription drugs that leave the normal distribution channel;

(b) upon receipt, each outside shipping container containing prescription drugs, prescription drug precursors, or prescription drug devices shall be visibly examined for identity and to prevent the acceptance of prescription drugs, prescription drug precursors, or prescription drug devices that are contaminated, reveal damage to the containers or are otherwise unfit for distribution:

(i) prescription drugs, prescription drug precursors, or prescription drug devices that are outdated, damaged, deteriorated, misbranded, adulterated or in any other way unfit for distribution or use in manufacturing shall be quarantined and physically separated from other prescription drugs, prescription drug precursors or prescription drug devices until they are appropriately destroyed or returned to their supplier; and

(ii) any prescription drug or prescription drug precursor whose immediate sealed or outer secondary sealed container has been opened or in any other way breached shall be identified as such and shall be quarantined and physically separated from other prescription drugs and prescription drug precursors until they are appropriately destroyed or returned to their supplier;

(c) each outgoing shipment shall be carefully inspected for identity of the prescription drug products or devices and to ensure that there is no delivery of prescription drugs or devices that have been damaged in storage or held under improper conditions:

(i) if the conditions or circumstances surrounding the return of any prescription drug or prescription drug precursor cast any doubt on the product's safety, identity, strength, quality or purity, then the drug shall be appropriately destroyed or returned to the supplier, unless examination, testing or other investigation proves that the product meets appropriate and applicable standards related to the product's safety, identity, strength, quality and purity;

(ii) returns of expired, damaged, recalled, or otherwise non-saleable prescription drugs shall be distributed by the receiving pharmaceutical wholesale distributor only to the original manufacturer or a third party returns processor that is licensed as a pharmaceutical wholesale distributor under this chapter;

(iii) returns or exchanges of prescription drugs (saleable or otherwise), including any redistribution by a receiving pharmaceutical wholesaler, shall not be subject to the pedigree requirements, so long as they are exempt from the pedigree requirement under the FDA's Prescription Drug Marketing Act guidance or regulations; and

(d) licensee under this Act and pharmacies or other persons authorized by law to dispense or administer prescription drugs for use by a patient shall be accountable for administering their returns process and ensuring that all aspects of their operation are secure and do not permit the entry of adulterated and counterfeit prescription drugs.

(12) A manufacturer or pharmaceutical wholesaler shall furnish prescription drugs only to a person licensed by the Division or to another appropriate state licensing authority to possess, dispense or administer such drugs for use by a patient.

(13) Prescription drugs furnished by a manufacturer or pharmaceutical wholesaler shall be delivered only to the business address of a person described in Subsections R156-17b-102(20)(c) and R156-17b-615, or to the premises listed on the license, or to an authorized person or agent of the licensee at the premises of the manufacturer or pharmaceutical wholesaler if the identity and authority of the authorized agent is properly established.

(14) Each facility shall establish and maintain records of all transactions regarding the receipt and distribution or other disposition of prescription drugs and prescription drug precursors and shall make inventories of prescription drugs and prescription drug precursors and required records available for inspection by authorized representatives of the federal, state and local law enforcement agencies in accordance with the following:

(a) there shall be a record of the source of the prescription drugs or prescription drug precursors to include the name and principal address of the seller or transferor and the address of the location from which the drugs were shipped;

(b) there shall be a record of the identity and quantity of the prescription drug or prescription drug precursor received, manufactured, distributed or shipped or otherwise disposed of by specific product and strength;

(c) there shall be a record of the dates of receipt and distribution or other disposal of any product;

(d) there shall be a record of the identity of persons to whom distribution is made to include name and principal address of the receiver and the address of the location to which the products were shipped;

(e) inventories of prescription drugs and prescription drug precursors shall be made available during regular business hours to authorized representatives of federal, state and local law enforcement authorities;

(f) required records shall be made available for inspection during regular business hours to authorized representatives of federal, state and local law enforcement authorities and such records shall be maintained for a period of two years following disposition of the products; and

(g) records that are maintained on site or immediately retrievable from computer or other electronic means shall be made readily available for authorized inspection during the retention period; or if records are stored at another location, they shall be made available within two working days after request by an authorized law enforcement authority during the two year period of retention.

(15) Each facility shall establish, maintain and adhere to written policies and procedures that shall be followed for the receipt, security, storage, inventory, manufacturing, distribution or other disposal of prescription drugs or prescription drug precursors, including policies and procedures for identifying, recording and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. In addition, the policies shall include the following:

(a) a procedure whereby the oldest approved stock of a prescription drug or precursor product is distributed or used first with a provision for deviation from the requirement if such deviation is temporary and appropriate;

(b) a procedure to be followed for handling recalls and withdrawals of prescription drugs adequate to deal with recalls and withdrawals due to:

(i) any action initiated at the request of the FDA or other federal, state or local law enforcement or other authorized administrative or regulatory agency;

(ii) any voluntary action to remove defective or potentially defective drugs from the market; or

(iii) any action undertaken to promote public health, safety or welfare by replacement of existing product with an improved product or new package design;

(c) a procedure to prepare for, protect against or handle any crisis that affects security or operation of any facility in the event of strike, fire, flood or other natural disaster or other situations of local, state or national emergency;

(d) a procedure to ensure that any outdated prescription drugs or prescription drug precursors shall be segregated from other drugs or precursors and either returned to the manufacturer, other appropriate party or appropriately destroyed;

(e) a procedure for providing for documentation of the disposition of outdated, adulterated or otherwise unsafe prescription drugs or prescription drug precursors and the maintenance of that documentation available for inspection by authorized federal, state or local authorities for a period of five years after disposition of the product;

(f) a procedure for identifying, investigating and reporting significant drug inventory discrepancies (involving counterfeit drugs suspected of being counterfeit, contraband, or suspect of being contraband) and reporting of such discrepancies within three (3) business days to the Division and/or appropriate federal or state agency upon discovery of such discrepancies; and

(g) a procedure for reporting criminal or suspected criminal activities involving the inventory of drugs and devices to the Division, FDA and if applicable, Drug Enforcement Administration (DEA), within three (3) business days.

(16) Each facility shall establish, maintain and make available for inspection by authorized federal, state and local law enforcement authorities, lists of all officers, directors, managers and other persons in charge which lists shall include a description of their duties and a summary of their background and qualifications.

(17) Each facility shall comply with laws including:

(a) operating within applicable federal, state and local laws and regulations;

(b) permitting the state licensing authority and authorized federal, state and local law enforcement officials, upon presentation of proper credentials, to enter and inspect their premises and delivery vehicles and to audit their records and written operating policies and procedures, at reasonable times and in a reasonable manner, to the extent authorized by law; and

(c) obtaining a controlled substance license from the Division and registering with the Drug Enforcement Administration (DEA) if they engage in distribution or manufacturing of controlled substances and shall comply with all federal, state and local regulations applicable to the distribution or manufacturing of controlled substances.

(18) Each facility shall be subject to and shall abide by applicable federal, state and local laws that relate to the salvaging or reprocessing of prescription drug products.

(19)(a) A Class C pharmacy may not be located in the same building as a separately licensed Class A, B, D, or E pharmacy unless:

(i) the separately licensed pharmacy is a third-party logistics provider; or

(ii) the two pharmacies are located in different suites as recognized by the United States Postal Service.

(b) Two Class C pharmacies may be located at the same address in the same suite if the pharmacies:

- (i) are under the same ownership;
- (ii) have processes and systems for separating and securing all aspects of the operation; and
- (iii) have traceability with a clear audit trail that distinguishes a pharmacy's purchases and distributions.

R156-17b-616. Operating Standards - Class D Pharmacy - Out of State Mail Service Pharmacies.

- (1) In accordance with Subsections 58-1-301(3) and 58-17b-306(2), an application for licensure as a Class D pharmacy shall include:
 - (a) a pharmacy care protocol that includes the operating standards established in Subsections R156-17b-610(1) and (8) and R156-17b-612(1) through (4);
 - (b) a copy of the pharmacist's license for the PIC; and
 - (c) a copy of the most recent state inspection or NABP inspection completed as part of the NABP Verified Pharmacy Program (VPP) showing the status of compliance with the laws and regulations for physical facility, records and operations.
- (2) An out of state mail service pharmacy that compounds shall follow the USP-NF Chapter 795 Compounding of non-sterile preparations and Chapter 797 Compounding of sterile preparations.

R156-17b-617a. Operating Standards - Class E Pharmacy - General Provisions.

- (1) In accordance with Section 58-17b-302 and Subsection 58-17b-601(1), Class E pharmacies shall have a written pharmacy care protocol that includes:
 - (a) the identity of the supervisor or director;
 - (b) a detailed plan of care;
 - (c) the identity of the drugs to be purchased, stored, used, or accounted for; and
 - (d) the identity of any licensed healthcare provider associated with the operation.
- (2) Class E pharmacies shall comply with all applicable federal and state laws.

R156-17b-617b. Class E Pharmacy Operating Standards - Analytical Laboratory.

In accordance with Section 58-17b-302 and Subsection 58-17b-601(1), an analytical laboratory shall:

- (1) be of suitable size and construction to facilitate cleaning, maintenance and proper operations;
- (2) provide adequate lighting, ventilation, sanitation, space, equipment and security conditions;
- (3) maintain a list of drugs that will be purchased, stored, used and accounted for;
- (4) maintain a list of licensed healthcare providers associated with the operation of the business;
- (5) possess prescription drugs for the purpose of analysis; and
- (6) take measures to prevent the theft or loss of controlled substances.

R156-17b-617c. Class E Pharmacy Operating Standards - Animal Control or Animal Narcotic Detection Training.

- (1) In accordance with Section 58-17b-302 and Subsection 58-17b-601(1), an animal control or animal narcotic detection training facility shall:
 - (a) maintain for immediate retrieval a perpetual inventory of all drugs including controlled substances that are purchased, stored, processed and administered;
 - (b) maintain for immediate retrieval a current list of authorized employees and their training with regards to the handling and use of legend drugs and/or controlled substances in relation to euthanasia, immobilization, or narcotic detection training of animals;
 - (c) maintain, for immediate retrieval documentation of all required materials pertaining to legitimate animal scientific drug research, guidance policy and other relevant documentation from the agency's Institutional Review Board, if applicable;
 - (d) maintain stocks of legend drugs and controlled substances to the smallest quantity needed for efficient operation to conduct animal euthanasia, immobilization, or narcotic detection training purposes;
 - (e) maintain all legend drugs and controlled substances in an area within a building having perimeter security that limits access during working hours, provides adequate security after working hours, and has the following security controls:
 - (i) a permanently secured safe or steel cabinet substantially constructed with self-closing and self-locking doors employing either multiple position combination or key lock type locking mechanisms; and
 - (ii) requisite key control, combination limitations, and change procedures;
 - (f) have a responsible party who is the only person authorized to purchase and reconcile legend drugs and controlled substances and is responsible for the inventory of the animal control or animal narcotic detection training facility pharmacy;
 - (g) ensure that only defined and approved individuals pursuant to the written facility protocol have access to legend drugs and controlled substances; and
 - (h) develop and maintain written policies and procedures for immediate retrieval that include the following:
 - (i) the type of activity conducted with regards to legend drugs and/or controlled substances;
 - (ii) how medications are purchased, inventoried, prepared and used in relation to euthanasia, immobilization, or narcotic detection training of animals;
 - (iii) the type, form and quantity of legend drugs and/or controlled substances handled;
 - (iv) the type of safe or equally secure enclosures or other storage system used for the storage and retrieval of legend drugs and/or controlled substances;
 - (v) security measures in place to protect against theft or loss of legend drugs and controlled substances;
 - (vi) adequate supervision of employees having access to manufacturing and storage areas;

(vii) maintenance of records documenting the initial and ongoing training of authorized employees with regard to all applicable protocols;

(viii) maintenance of records documenting all approved and trained authorized employees who may have access to the legend drugs and controlled substances; and

(ix) procedures for allowing the presence of business guests, visitors, maintenance personnel, and non-employee service personnel.

R156-17b-617d. Class E Pharmacy Operating Standards- Durable Medical Equipment.

- (1) In accordance with Section 58-17b-302 and Subsection 58-17b-601(1), durable medical equipment facility shall:
 - (a) be of suitable size and construction to facilitate cleaning, maintenance and proper operations;
 - (b) provide adequate lighting, ventilation, sanitation, space, equipment and security conditions;
 - (c) be equipped to permit the orderly storage of durable medical equipment in a manner to permit clear identification, separation and easy retrieval of products and an environment necessary to maintain the integrity of the product inventory;
 - (d) be equipped to permit practice within the standards and ethics of the profession as dictated by the usual and ordinary scope of practice to be conducted within that facility;
 - (e) maintain prescription forms and records for a period of five years;
 - (f) be locked and enclosed in such a way as to bar entry by the public or any non-personnel when the facility is closed; and
 - (g) post the license of the facility in full view of the public.
- (2) A licensed practitioner who administers durable medical equipment to a patient or animal is not engaging in the practice of pharmacy, and does not require a license as a Class E pharmacy.

R156-17b-617e. Class E Pharmacy Operating Standards - Human Clinical Investigational Drug Research Facility.

(1) In accordance with Section 58-17b-302 and Subsection 58-17b-601(1), a human clinical investigational drug research facility licensed as a Class E Pharmacy shall, in addition to the requirements contained in Subsection R156-17b-617a, conduct operations in accordance with the operating standards set forth in 21 CFR Part 312, April 1, 2012 edition, which are hereby incorporated by reference.

(2) In accordance with Subsections 58-37-6(2)(b) and (3)(a)(i), persons licensed to conduct research with controlled substances in Schedules I-V within this state may possess, manufacture, produce, distribute, prescribe, dispense, administer, conduct research with, or perform laboratory analysis upon those substances to the extent authorized by their license.

(3) In accordance with Subsection 58-37-6(2), the following persons are not required to obtain a license and may lawfully possess controlled substances included in Schedules II-V:

- (a) an agent or employee acting in the usual course of the person's business or employment, and
- (b) an ultimate user, or any person who possesses any controlled substance pursuant to a lawful order of a practitioner.
- (4) A separate license is required at each principal place of business or professional practice where the applicant manufactures, produces, distributes, dispenses, conducts research with, or performs laboratory analysis upon controlled substances.

R156-17b-617f. Class E Pharmacy Operating Standards - Medical Gas Provider.

In accordance with Section 58-17b-302 and Subsection 58-17b-601(1), a medical gas facility shall:

- (a) develop standard operating policy and procedures manual;
- (b) conduct training and maintain evidence of employee training programs and completion certificates;
- (c) maintain documentation and records of all transactions to include:
 - (i) batch production records
 - (ii) certificates of analysis
 - (iii) dates of calibration of gauges;
- (d) provide adequate space for orderly placement of equipment and finished product;
- (e) maintain gas tanks securely;
- (f) designate return and quarantine areas for separation of products;
- (g) label all products;
- (h) fill cylinders without using adapters; and
- (i) comply with all FDA standards and requirements.

R156-17b-617g. Operating Standards - Class E Pharmacy - Third Party Logistics Provider.

- (1) A third party logistics provider shall comply with storage practices for facilitating, including:
 - (a) access to warehouse space of suitable size to facilitate safe operations, including a suitable area to quarantine suspect product;
 - (b) adequate security; and
 - (c) written policies and procedures to:
 - (i) address receipt, security, storage, inventory, shipment, and distribution of a product;
 - (ii) identify, record, and report confirmed losses or thefts in the United States;
 - (iii) correct errors and inaccuracies in inventories;
 - (iv) provide support for manufacturer recalls;

(v) prepare for, protect against, and address any reasonably foreseeable crisis that affects security or operation at the facility, such as a strike, fire, or flood;

(vi) ensure that any expired product is segregated from other products and returned to the manufacturer or reverse distributor;

(vii) maintain the capability to trace the receipt and outbound distribution of a product, and supplies and records of inventory;

and

(viii) quarantine or destroy a suspect product if directed to do so by the respective manufacturer, wholesale distributor, dispenser, or an authorized government agency.

(2) A third party logistics provider may not employ at its facility an individual who has been convicted of a felony violation relating to product tampering.

R156-17b-618. Change in Ownership or Location.

(1) In accordance with Section 58-17b-614, except for changes in ownership caused by a change in the stockholders in corporations that are publicly listed and whose stock is publicly traded, a licensed pharmaceutical facility shall make application for a new license and receive approval from the Division no later than ten business days prior to any of the following proposed changes:

(a) location or address, except for a reassignment of a new address by the United States Postal Service that does not involve any change of location;

(b) name, except for a doing-business-as (DBA) name change that is properly registered with the Division of Corporations and filed with the Division of Occupational and Professional Licensing; or

(c) ownership when one of the following occurs:

(i) a change in entity type; or

(ii) the sale or transfer of 51% or more of an entity's ownership or membership interest to another individual or entity.

(2) Upon approval of the change in location, name, or ownership, and the issuance of a new license, the original license shall be surrendered to the Division.

(3) Upon approval of the name change, the original licenses shall be surrendered to the Division.

R156-17b-619. Operating Standards - Third Party Payors.

Reserved.

R156-17b-620. Operating Standards - Automated Pharmacy System.

In accordance with Section 58-17b-621, automated pharmacy systems can be utilized in licensed pharmacies, remote locations under the jurisdiction of the Division and licensed health care facilities where legally permissible and shall comply with the following provisions:

(1) Documentation as to type of equipment, serial numbers, content, policies and procedures and location shall be maintained on site in the pharmacy for review upon request of the Division. Such documentation shall include:

(a) name and address of the pharmacy or licensed health care facility where the automated pharmacy system is being used;

(b) manufacturer's name and model;

(c) description of how the device is used;

(d) quality assurance procedures to determine continued appropriate use of the automated device; and

(e) policies and procedures for system operation, safety, security, accuracy, patient confidentiality, access and malfunction.

(2) Automated pharmacy systems should be used only in settings where there is an established program of pharmaceutical care that ensures that before dispensing, or removal from an automated storage and distribution device, a pharmacist reviews all prescription or medication orders unless a licensed independent practitioner controls the ordering, preparation and administration of the medication; or in urgent situations when the resulting delay would harm the patient including situations in which the patient experiences a sudden change in clinical status.

(3) All policies and procedures must be maintained in the pharmacy responsible for the system and, if the system is not located within the facility where the pharmacy is located, at the location where the system is being used.

(4) Automated pharmacy systems shall have:

(a) adequate security systems and procedures to:

(i) prevent unauthorized access;

(ii) comply with federal and state regulations; and

(iii) prevent the illegal use or disclosure of protected health information;

(b) written policies and procedures in place prior to installation to ensure safety, accuracy, security, training of personnel, and patient confidentiality and to define access and limits to access to equipment and medications.

(5) Records and electronic data kept by automated pharmacy systems shall meet the following requirements:

(a) all events involving the contents of the automated pharmacy system must be recorded electronically;

(b) records must be maintained by the pharmacy for a period of five years and must be readily available to the Division.

Such records shall include:

(i) identity of system accessed;

(ii) identity of the individual accessing the system;

(iii) type of transaction;

(iv) name, strength, dosage form and quantity of the drug accessed;

(v) name of the patient for whom the drug was ordered; and

- (vi) such additional information as the PIC may deem necessary.
- (6) Access to and limits on access to the automated pharmacy system must be defined by policy and procedures and must comply with state and federal regulations.
- (7) The PIC or pharmacist designee shall have the responsibility to ensure that:
 - (a) user access to the system is assigned, discontinued or changed according to employment status and credentials;
 - (b) access to the medications comply with state and federal regulations; and
 - (c) the automated pharmacy system is filled and stocked accurately and in accordance with established written policies and procedures.
- (8) The filling and stocking of all medications in the automated pharmacy system shall be accomplished by qualified licensed healthcare personnel under the supervision of a licensed pharmacist.
- (9) A record of medications filled and stocked into an automated pharmacy system shall be maintained for a period of five years and shall include the identification of the persons filling, stocking and checking for accuracy.
- (10) All containers of medications stored in the automated pharmacy system shall be packaged and labeled in accordance with federal and state laws and regulations.
- (11) All aspects of handling controlled substances shall meet the requirements of all state and federal laws and regulations.
- (12) The automated pharmacy system shall provide a mechanism for securing and accounting for medications removed from and subsequently returned to the automated pharmacy system, all in accordance with existing state and federal law. Written policies and procedures shall address situations in which medications removed from the system remain unused and must be secured and accounted for.
- (13) The automated pharmacy system shall provide a mechanism for securing and accounting for wasted medications or discarded medications in accordance with existing state and federal law. Written policies and procedures shall address situations in which medications removed from the system are wasted or discarded and must be secured.

R156-17b-621. Operating Standards - Pharmacist, Pharmacy Intern, and Pharmacy Technician Administration - Training.

In accordance with Subsections 58-17b-102(53), (56), and (57), and 58-17b-502(1)(i):

- (1) A pharmacist or pharmacy intern who will administer a prescription drug or device shall complete the following appropriate training prior to engaging in administration:
 - (a) current Basic Life Support (BLS) certification;
 - (b) for injectable drugs, didactic and practical training for administering injectable drugs;
 - (c) topics related to the specific prescription drug or device that will be administered;
 - (d) if administering vaccines, current guidelines from the Advisory Committee on Immunization Practices (ACIP) of the U.S. Centers for Disease Control and Prevention (CDC); and
 - (e) the management of an anaphylactic reaction.
- (2) A pharmacy technician who will administer a prescription drug or device shall complete the appropriate training described in Subsections 1)(a), (b), and (e) prior to engaging in administration.
- (3) Sources for the appropriate training include:
 - (a) ACPE approved programs;
 - (b) curriculum-based programs from an ACPE accredited college of pharmacy, or an ASHP accredited pharmacy technician program;
 - (c) state or local health department programs; and
 - (d) other Board recognized providers.
- (4) An individual who engages in the administration of prescription drugs or devices shall:
 - (a) maintain documentation that they obtained their required training; and
 - (b) for each renewal cycle after their initial training, complete at least two hours of continuing education related to their administration of prescription drugs or devices, in accordance with Section R156-17b-309.
- (5) The "Vaccine Administration Protocol: Standing Order to Administer Immunizations and Emergency Medications", adopted March 26, 2019, by the Division in collaboration with the Utah State Board of Pharmacy and the Utah Physicians Licensing Board, as posted on the Division website, is the guideline or standard for pharmacist administration of vaccines and emergency medications, and for pharmacy intern or pharmacy technician administration pursuant to delegation by a pharmacist.

R156-17b-621a. Operating Standards - Pharmacist Administration of a Long-acting Injectable and Naloxone - Training.

In accordance with Subsections 58-17b-502(1)(i) and 58-17b-625(2):

- (1) Prior to engaging in the administration of a long-acting injectable drug pursuant to Section 58-17b-625, a pharmacist shall successfully complete:
 - (a) current Basic Life Support (BLS) certification; and
 - (b) a training program for administering long-acting injectables intramuscularly that is provided by an ACPE-accredited provider.
- (2) An individual who engages in the administration of long-acting injectable drugs intramuscularly shall maintain documentation that they obtained their required training.

R156-17b-621b. Operating Standards - Pharmacist and Pharmacy Intern Dispensing of a Self-Administered Hormonal Contraceptive - Training.

In accordance with Subsection 58-17b-502(n) and Section 26-64-106:

(1) Prior to dispensing a self-administered hormonal contraceptive, a pharmacist or pharmacy intern shall successfully complete a training program for dispensing self-administered hormonal contraceptives that is provided by an ACPE-accredited provider and approved by the Division in collaboration with the Board.

(2) A pharmacist or pharmacy intern who engages in the dispensing of a self-administered hormonal contraceptive shall:

(a) maintain documentation that they obtained their required training prior to any dispensing; and
(b) for each renewal cycle after the initial training, successfully complete a minimum of two hours of continuing education related to dispensing a self-administered hormonal contraceptive, in accordance with Section R156-17b-309.

(3) The Utah Hormonal Contraceptive Self-screening Risk Assessment Questionnaire, adopted September 18, 2018, posted on the Division's website, is the self-screening risk assessment questionnaire to be used for pharmacist and pharmacy intern dispensing of self-administered hormonal contraceptives.

R156-17b-622. Standards - Dispensing Training Program.

(1) In accordance with Subsection R156-17b-102(18), a formal or on-the-job dispensing training program completed by a DMP designee is one that covers the following topics to the extent that the topics are relevant and current to the DMP practice where the DMP designee is employed:

- (a) role of the DMP designee;
- (b) laws affecting prescription drug dispensing;
- (c) pharmacology including the identification of drugs by trade and generic names, and therapeutic classifications;
- (d) pharmaceutical terminology, abbreviations and symbols;
- (e) pharmaceutical calculations;
- (f) drug packaging and labeling;
- (g) computer applications in the pharmacy;
- (h) sterile and non-sterile compounding;
- (i) medication errors and safety;
- (j) prescription and order entry and fill process;
- (k) pharmacy inventory management; and
- (l) pharmacy billing and reimbursement.

(2) Documentation demonstrating successful completion of a formal or on-the-job dispensing training program shall include the following information:

- (a) name of individual trained;
- (b) name of individual or entity that provided training;
- (c) list of topics covered during the training program; and
- (d) training completion date.

R156-17b-623. Standards - Approved Cosmetic Drugs and Injectable Weight Loss Drugs for Dispensing Medical Practitioners.

The drugs that may be dispensed by a DMP in accordance with Subsection 58-17b-802(1) and Section 58-17b-803 are limited to:

- (1) the following cosmetic drugs:
 - (a) Latisse; and
 - (b) the injectable weight loss drug human chorionic gonadotropin; and
- (2) the legend, non-controlled drugs approved under Section R156-83-306 for prescribing by an online prescriber.

R156-17b-624. Operating Standards. Repackaged or Compounded Prescription Drugs - Sale to a Practitioner for Office Use.

Pursuant to Section 58-17b-624, a pharmacy may repackage or compound a prescription drug for sale to a practitioner for office use provided that it is in compliance with all applicable federal and state laws and regulations regarding the practice of pharmacy, including, but not limited to the Food, Drug, and Cosmetic Act, 21 U.S.C.A 301 et seq.

R156-17b-625. Standards - Reporting and Maintaining Records on the Dispensing of an Opiate Antagonist.

(1) In accordance with Subsections 26-55-105(2)(c) and (d), the pharmacist-in-charge or a responsible corporate officer of each pharmacy licensee that dispenses an opiate antagonist pursuant to a valid standing prescription drug order issued by a physician, shall affirm that the pharmacy licensee has complied with the protocol for dispensing an opiate antagonist as set forth in Section 26-55-105, and shall report, on an annual basis, to the division and to the physician who issued the opiate antagonist standing drug order, the following information:

(a) the total number of single doses of opiate antagonists dispensed during the reporting period; and
(b) the name of each opiate antagonist dispensed, along with the total number of single doses of that particular named opiate antagonist.

(2) Corporations or organizations with multiple component pharmacy licenses may submit one cumulative report for all its component pharmacy licensees. However, that report must contain the information described above for each of the component pharmacy licensees.

(3) Null reporting is not required. If a pharmacy licensee does not dispense an opiate antagonist during any year, that pharmacy licensee is not required to make an affirmation or report to the division.

(4) The annual affirmation and report described above is due to the division and to the physician who issued the standing drug order no later than 15 days following December 31 of each calendar year.

(5) In accordance with Subsection 26-55-105(2)(d), a pharmacy licensee who dispenses an opiate antagonist pursuant to a valid standing prescription order issued by a physician, shall maintain, subject to audit, the following information:

- (a) the name of the individual to whom the opiate antagonist is dispensed;
- (b) the name of the opiate antagonist dispensed;
- (c) the quantity of the opiate antagonist dispensed;
- (d) the strength of the opiate antagonist dispensed;
- (e) the dosage quantity of the opiate antagonist dispensed;
- (f) the full name of the drug outlet which dispensed the opiate antagonist;
- (g) the date the opiate antagonist was dispensed; and
- (h) the name of physician issuing the standing order to dispense the opiate antagonist.

(6) The division approves the protocol for the issuance of a standing prescription drug order for opiate antagonists, which is set forth in Subsection 26-55-105(2)(a) through (d) along with the requirements set forth in the foregoing provisions, and the reporting requirements set forth in Sections R156-67-604 and R156-68-604.

R156-17b-626. Operating Standards - Appropriate Substitutes for Albuterol.

(1) In accordance with Subsections 58-17b-601(1) and 58-17b-605(9), a pharmacist or pharmacy intern may make appropriate substitutes for an albuterol inhaler with any brand or proprietary name albuterol product that has the same milligram dose per actuation.

(2) The pharmacist or pharmacy intern shall document an albuterol substitution on the prescription hard copy or in the medication profile system.

R156-17b-627. Operating Standards - Prescription of Drugs or Devices by a Pharmacist.

(1) In accordance with Subsection 58-17b-601(1) and Section 58-17b-627, a pharmacist from a Class A or Class B pharmacy may prescribe a prescription drug or device as follows:

(a) Prior to prescribing, the pharmacist shall conduct a patient assessment that includes:

- (i) current health status;
- (ii) past medical history;
- (iii) allergies;
- (iv) medication sensitivities;
- (v) rationale for care;
- (vi) current medication; and
- (vii) if the pharmacist should refer the patient to an appropriate health care provider or otherwise encourage the patient

to seek further medical care.

(b) The pharmacist shall follow the guidelines for prescribing health care providers established by:

- (i) the Centers for Disease Control and Prevention;
- (ii) nationally accepted guidelines; and
- (iii) the Department of Health and the Division in collaboration with the Board, in the guidance documents incorporated by reference in Subsection (2).

(c) The pharmacist shall comply with the requirements of Sections 58-17b-602 and 58-17b-609.

(d) The pharmacist shall develop and implement an appropriate follow-up care plan with the patient that includes:

- (i) monitoring parameters for efficacy and safety;
- (ii) adverse reactions; and
- (iii) further medical care.

(e)(i)(A) The pharmacist shall notify the patient's primary care or other health care provider about the prescription within five business days of the prescribing.

(B) The prescription notification may be conveyed in writing, by electronic transmission, or by telephone.

(C) If the patient does not have a primary care or other health care provider, the pharmacist shall provide the prescription notification to the patient.

(D) The pharmacy shall maintain the prescription notification in the patient record for at least five years from the date of notification, in an immediately retrievable written or electronic format.

(ii) Each prescription notification shall include the following:

- (A) prescribing pharmacist;
- (B) pharmacy name;
- (C) pharmacy phone number;
- (D) patient;
- (E) patient date of birth;
- (F) drug or device;
- (G) if dispensed, dispensed quantity;
- (H) directions for use;
- (I) refill; and

- (J) identity of the patient's primary care or other health care provider, if any.
- (2)(a) A pharmacist may prescribe drugs or devices under Subsection 58-17b-627(3)(a) as established in the following guidance documents posted on the Division's website at dopl.utah.gov/pharm:
 - (i) Utah Guidance for Pre-Exposure and Post-Exposure Prophylaxis of HIV, adopted September 28, 2021;
 - (ii) Utah Guidance for Self-Administered Hormonal Contraceptives, adopted September 28, 2021;
 - (iii) Utah Guidance for Tobacco Cessation Products, adopted September 28, 2021; and
 - (iv) Utah Guidance for Naloxone, adopted September 28, 2021.
- (b) The Division incorporates by reference the guidance documents in Subsection (2)(a).
- (3) The Division in collaboration with the Board shall review the guidance documents in Subsection (2) on a biennial basis, in collaboration with the individuals identified in Subsection 58-17b-627(4) and other persons as determined by the Division in collaboration with the Board.
- (4)(a) Beginning June 2022 and commencing annually thereafter, the Department of Health may submit to the Division a written proposal that includes:
 - (i) in accordance with Subsection 58-17b-627(3)(a), designated public health concerns that the Department of Health has determined can be addressed through pharmacist prescribing of drugs or devices; and
 - (ii) any recommendations for updates to the guidance documents in Subsection (2).
- (b) After receipt of the Department of Health's annual designation, the Division:
 - (i) shall contact the Department of Health to review its proposal; and
 - (ii) may review the rules made by the Division, including the guidance documents in Subsection (2), in accordance with Subsections 58-17b-627(3) and (4).
- (5) The Division shall review the guidance documents in Subsection (2) on a biennial basis, in collaboration with:
 - (a) the Board;
 - (b) the individuals identified in Subsection 58-17b-627(4); and
 - (c) other persons as determined by the Division.

R156-17b-901. Operating Standards - Charitable Prescription Drug Recycling Program.

- (1) In accordance with Sections 58-17b-903 and 58-17b-907, the operating standards for implementation of the Charitable Prescription Drug Recycling Program under Title 58, Chapter 17b, Part 9, Charitable Prescription Drug Recycling Act, are established in this section.
- (2) The Division in collaboration with the board has not established a date later than the beyond use date or the expiration date recommended by the manufacturer for a specific prescription drug.
- (3) As authorized by Subsection 58-17b-905(2)(e), an eligible pharmacy may charge the following handling fees:
 - (a) before accepting a prescription drug under the program: \$0 - \$10; and
 - (b) before dispensing a prescription drug under the program: \$0 - \$5.
- (4) A pharmacy seeking registration with the Division as an eligible pharmacy shall submit an application on a form provided by the Division and establish that:
 - (a) the applicant is currently licensed and in good standing with the Division;
 - (b) the applicant agrees to maintain, subject to inspection by the Division, written standards and procedures in compliance with Subsection (6);
 - (c) the applicant agrees to create and maintain, subject to inspection by the Division, a special training program in accordance with Subsection (8); and
 - (d) the applicant meets the requirements of Subsection 58-17b-902(8)(b).
- (5) The formulary established under Subsection 58-17b-907(2) shall include each prescription drug approved by the federal Food and Drug Administration that meet Section 58-17b-904 criteria, except for:
 - (a) controlled substances;
 - (b) compounded drugs; and
 - (c) drugs that can only be dispensed to a patient registered with the drug's manufacturer per federal Food and Drug Administration requirements.
- (6) An eligible pharmacy shall maintain written standards and procedures available for inspection by the division that:
 - (a) satisfy the requirements of Section 58-17b-907; and
 - (b) satisfy labeling requirements of Subsections 58-17b-602(5) through (8), and ensure that labels clearly identify the eligible drug was dispensed under the program.
- (7)(a) In accordance with Subsection 58-17b-907(4)(a), the division shall schedule and facilitate an annual meeting between the Department of Health and eligible pharmacies to establish program standards and procedures for assisted living facilities and nursing care facilities.
- (b) In accordance with Subsection 58-17b-907(4)(b), the division shall schedule and facilitate an annual meeting between the Division of Substance Abuse and Mental Health and eligible pharmacies to establish program standards and procedures for mental health and substance abuse clients.
- (8) An eligible pharmacy shall:
 - (a) create and maintain a special training program that its pharmacists and licensed pharmacy technicians shall complete before participating in the program; and

(b) maintain a record for at least two years of each pharmacist and licensed pharmacy technician that has completed the special training program.

KEY: pharmacists, licensing, pharmacies

Date of Last Change: January 27, 2022

Notice of Continuation: September 5, 2019

Authorizing, and Implemented or Interpreted Law: 58-17b-101; 58-17b-601(1); 58-37-1; 58-1-106(1)(a); 58-1-202(1)(a)