

R156-17b. Pharmacy Practice Act Rule.

R156-17b-102. Definitions.

In addition to the definitions in Title 58, Chapters 1 and 17b, as used in Title 58, Chapters 1 and 17b or this rule:

(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 the purpose of 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 between such pharmaceutical wholesaler and a manufacturer, as defined in Section 1504 of the Internal Revenue Code, when the pharmaceutical wholesaler has a written agreement currently in effect with the manufacturer evidencing such ongoing relationship, and the pharmaceutical wholesaler 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 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 that have the same common ownership and control.

(9) "Clinic" as used in Subsection 58-17b-625(3)(b) means a class B pharmacy, or a facility which provides out-patient health care services whose primary practice includes the therapeutic use of drugs related to a

specific patient for the purpose of:

- (a) curing or preventing the patient's disease;
- (b) eliminating or reducing the patient's disease;
- (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 FDA's implementation of the Prescription Drug Marketing Act as applicable.

(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) "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.

(14) "Counterfeit prescription drug" has the meaning given that term in 21 USC 321(g)(2), including any amendments thereto.

(15) "Counterfeiting" means engaging in activities that create a counterfeit prescription drug.

(16) "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.

(17) "Device" means an instrument, apparatus, implement, machine, contrivance, implant, or other similar or related article, including any component part or accessory, which is required under Federal law to bear the label, "Caution: Federal or State law requires dispensing by or on the order of a physician."

(18) "DMP" means a dispensing medical practitioner licensed under Title 58, Chapter 17b, Part 8.

(19) "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 established in Subsection 58-17b-803(4)(c);

and

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

(20) "DMPIC" means a dispensing medical practitioner licensed under

Title 58, Chapter 17b, Part 8 who is designated by a dispensing medical practitioner clinic pharmacy to be responsible for activities of the pharmacy.

(21) "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.

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

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

(24) "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.

(25) "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.

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

(27) "ExCPT", as used in this rule, means the Exam for the Certification of Pharmacy Technicians.

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

(29) "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.

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

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

(32) "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.

(33) "Legend drug" or "prescription drug" means any drug or device that has been determined to be unsafe for self-medication or any drug or device 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".

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

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

(36) [~~"Mail service retail pharmacy" means a retail pharmacy located in Utah that dispenses primarily through mailing or shipping.~~

~~(37)] "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. Such manufacturer's exclusive distributor shall be licensed as a pharmaceutical wholesaler under this chapter and be an "authorized distributor of record" to be considered part of the "normal distribution channel".~~

(3[8]7) "Medical supplies" means items for medical use that are suitable for use in a health care facility or in the home and that are disposable or semi-disposable and are non-reusable.

(3[9]8) "MPJE" means the Multistate Pharmacy Jurisprudence Examination.

([40]39) "NABP" means the National Association of Boards of Pharmacy.

(4[1]0) "NAPLEX" means North American Pharmacy Licensing Examination.

(4[2]1) "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.

(4[3]2) "Normal distribution channel" means a chain of custody for a prescription drug that goes directly, by drop shipment as defined in

Subsection (2[0]1), 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 under this chapter 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 under this chapter 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 under this chapter to dispense or administer such drug for use by a patient.

(4[4]3) "Other health care facilities" means any entity as defined in Utah Code Subsection 26-21-2(13)(a) or Utah Administrative Code R432-1-3(55).

(4[5]4) "Parenteral" means a method of drug delivery injected into body tissues but not via the gastrointestinal tract.

(4[6]5) "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 (40)(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 other medical facility that provides health care services.

(4[7]6) "Pedigree" means a document or electronic file containing information that records each distribution of any given prescription drug.

(4[8]7) "PIC", as used in this rule, means the pharmacist-in-charge.

(4[9]8) "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.

([50]49) "Prescription files" means all hard-copy and electronic prescriptions that includes pharmacist notes or technician notes, clarifications or information written or attached that is pertinent to the prescription.

(5[1]0) "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 (BSP Pharm) or a doctorate in pharmacy (PharmD).

(5[2]1) "PTCB" means the Pharmacy Technician Certification Board.

(5[3]2) "Qualified continuing education", as used in this rule, means continuing education that meets the standards set forth in Section R156-17b-309.

(5[4]3) "Refill" means to fill again.

(5[5]4) "Remote dispensing pharmacist-in-charge" or "RDPIC" mean the PIC of a remote dispensing pharmacy. The RDPIC shall be the PIC of the remote dispensing pharmacy's supervising pharmacy.

(5[6]5) "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.

(5[7]6) "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.

(5[8]7) "Research facility" means a facility where research takes place that has policies and procedures describing such research.

~~[(59) "Retail Pharmacy" as defined in Subsection 58-17b-102(67), is further clarified to mean a pharmaceutical facility that dispenses primarily to walk-in customers, and if applicable may deliver.~~

~~[(60)]~~ (58) "Reverse distributor" means a person or company that retrieves unusable or outdated drugs from a pharmacy for the purpose of removing those drugs from stock and destroying them.

([61]59) "Self-administered hormonal contraceptive" means the same as defined in Subsection 26-62-102(9).

(6[2]0) "Sterile products preparation facility" means any facility, or portion of the facility, that compounds sterile products using aseptic technique.

(6[3]1) "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.

(6[4]2) "Supervisor" means a licensed pharmacist or DMP in good standing with the Division.

(6[5]3) "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(6); or

(c) still image capture.

(6[6]4) "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.

(6[7]5) "Unauthorized personnel" means any person who is not participating in the operational processes of the pharmacy who in some way would interrupt the natural flow of pharmaceutical care.

(6[8]6) "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.

(6[9]7) "Unprofessional conduct", as defined in Title 58, Chapters 1 and 17b, is further defined, in accordance with Subsection 58-1-203(1)(e), in Section R156-17b-502.

([70]68) 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, as posted on the Division's website, is the self-screening risk assessment questionnaire approved by the Division pursuant to Section 26-62-106.

([71]69) "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.

(7[2]0) "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.

(7[3]1) "Wholesale distribution" means the distribution of drugs to persons other than consumers or patients, but does not include:

(a) intracompany sales or transfers;

(b) the sale, purchase, distribution, trade, or other transfer of a prescription drug for emergency medical reasons, as defined under 21 CFR 203.3(m), including any amendments thereto;

(c) the sale, purchase, or trade of a drug pursuant to a prescription;

(d) the distribution of drug samples;

(e) the return or transfer of prescription drugs to the original manufacturer, original wholesale distributor, reverse distributor, or a third party returns processor;

(f) the sale, purchase, distribution, trade, or transfer of a prescription drug from one authorized distributor of record to one additional authorized distributor of record during a time period for which there is documentation from the manufacturer that the manufacturer is able to supply a prescription drug and the supplying authorized distributor of record states in writing that the prescription drug being supplied had until that time been exclusively in the normal distribution channel;

(g) the sale, purchase or exchange of blood or blood components for transfusions;

(h) the sale, transfer, merger or consolidation of all or part of the business of a pharmacy;

(i) delivery of a prescription drug by a common carrier; or

(j) other transactions excluded from the definition of "wholesale distribution" under 21 CFR 203.3 (cc), including any amendments thereto.

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 be composed of seven members, who shall be diversified between retail pharmacy, hospital pharmacy, and other pharmacy specialties deemed pertinent by the Division in collaboration with the Board, and a physician knowledgeable about compounding and licensed in good standing in the state. All members shall have experience and knowledge of least one USP Chapter, USP <795>, USP <797>, or USP <800>.

(3) 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.

(4) 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;

(b) reviewing and making recommendations regarding pharmacy compounding education and training;

(c) reviewing and making recommendations regarding pharmacy compounding laws and rules; and

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

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

(6)(a) 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.

(b) The chair, vice chair, or their designee shall attend at least one Board meeting, one meeting of the physician licensing board, and one meeting of the osteopathic physician licensing board per calendar quarter to report the Committee's activities and recommendations to the Division and the ~~[Board]~~ boards.

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, which 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) ~~[general pharmacy;~~

~~(iv)]~~ patient safety; or

(iv) immunizations;

(c) one hour of pharmacy law or ethics;

(d) if engaging in the administration of ~~[immunizations or]~~ vaccines as defined in Section R156-17b-621, two hours in ~~[immunizations or]~~ 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 Sections 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 ~~[immunizations or]~~ vaccines as defined in Section R156-17b-621, two hours in ~~[immunizations or]~~ vaccine-related topics.

(b) Current PTCB or ExCPT certification shall fulfill all CE requirements for a pharmacy technician, except for [~~immunization~~]/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 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) All CE 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 any CE that cannot be tracked by the licensee's NABP plan.

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 all Class A and Class B pharmacies, which may be supplemented or amended by additional standards defined in this rule applicable to specific types of Class A and B pharmacies.

(1) The general operating standards include:

(a) be well lighted, well ventilated, clean and sanitary;

(b) if transferring a drug from a manufacturer's or distributor's original container to another container, the ~~[dispensing area, if any,]~~ pharmacy shall have a sink with hot and cold culinary water separate and apart from any restroom facilities. This does not apply to clean rooms where sterile products are prepared. Clean rooms may not have sinks or floor drains ~~[that expose the area to an open sewer]~~. All required equipment shall be clean and in good operating condition;

(c) be equipped to permit the orderly storage of prescription drugs and 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) 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 health, safety and welfare; and

(f) if dispensing controlled substances, be equipped with a security system to:

(i) permit detection of entry at all times when the facility is closed; and

(ii) provide notice of unauthorized entry to an individual; and

(g) be equipped with a lock on any entrances to the facility where drugs are stored.

(2) (a) Prescription labels for compounded sterile and non-sterile medications when dispensed to the ultimate user or agent shall include the minimum information required pursuant to Section 58-17b-602 and the following:

(i) generic name; and

(ii) quantity or concentration of each active ingredient.

(b) For sterile preparation of parental use, labeling shall include;

(i) the name of the base solution for infusion preparation;

(ii) assigned compounding record or lot number; and

(iii) "compounded preparation".

(b) The requirements described in Subsections (2)(a)(i) and (2)(b) do not apply to a label on the container of a drug that a health care provider administers to a patient at:

(i) a pharmaceutical administration facility; or

(ii) a hospital licensed under Title 26, Chapter 21, Health Care Facility Licensing and Inspection Act.

~~[(2)](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.

~~[(3) Facilities engaged in simple, moderate or complex non-sterile or any level of sterile compounding activities shall be required to maintain proper records and procedure manuals and establish quality control measures to ensure stability, equivalency where applicable and sterility. The following requirements shall be met:~~

~~(a) Facilities shall follow USP NF Chapter 795, compounding of non-sterile preparations, and USP NF Chapter 797 if compounding sterile preparations.~~

~~(b) Facilities may compound in anticipation of receiving prescriptions in limited amounts.~~

~~(c) Bulk active ingredients shall:~~

~~(i) be procured from a facility registered with the federal Food and Drug Administration; and~~

~~(ii) not be listed on the federal Food and Drug Administration list of drug products withdrawn or removed from the market for reasons of safety or effectiveness.~~

~~(d) All facilities that dispense prescriptions must comply with the record keeping requirements of their State Boards of Pharmacy. When a facility compounds a preparation according to the manufacturer's labeling instructions, then further documentation is not required. All other compounded preparations require further documentation as described in this section.~~

~~(e) A master formulation record shall be approved by a pharmacist or DMP for each batch of sterile or non-sterile pharmaceuticals to be prepared. Once approved, a duplicate of the master formulation record shall be used as the compounding record from which each batch is prepared and on which all documentation for that batch occurs. The master formulation record may be stored electronically and shall contain at a minimum:~~

~~(i) official or assigned name;~~

~~(ii) strength;~~

~~(iii) dosage form of the preparation;~~

~~(iv) calculations needed to determine and verify quantities of components and doses of active pharmaceutical ingredients;~~

~~(v) description of all ingredients and their quantities;~~

~~(vi) compatibility and stability information, including references~~

~~when available;~~

- ~~(vii) equipment needed to prepare the preparation;~~
- ~~(viii) mixing instructions, which shall include:~~
 - ~~(A) order of mixing;~~
 - ~~(B) mixing temperatures or other environmental controls;~~
 - ~~(C) duration of mixing; and~~
 - ~~(D) other factors pertinent to the replication of the preparation as compounded;~~

~~(ix) sample labeling information, which shall contain, in addition to legally required information:~~

- ~~(A) generic name and quantity or concentration of each active ingredient;~~
- ~~(B) assigned beyond use date;~~
- ~~(C) storage conditions; and~~
- ~~(D) prescription or control number, whichever is applicable;~~
- ~~(x) container used in dispensing;~~
- ~~(xi) packaging and storage requirements;~~
- ~~(xii) description of final preparation; and~~
- ~~(xiii) quality control procedures and expected results.~~

~~(f) A compounding record for each batch of sterile or non-sterile pharmaceuticals shall document the following:~~

- ~~(i) official or assigned name;~~
- ~~(ii) strength and dosage of the preparation;~~
- ~~(iii) Master Formulation Record reference for the preparation;~~
- ~~(iv) names and quantities of all components;~~
- ~~(v) sources, lot numbers, and expiration dates of components;~~
- ~~(vi) total quantity compounded;~~
- ~~(vii) name of the person who prepared the preparation;~~
- ~~(viii) name of the compounder who approved the preparation;~~
- ~~(ix) name of the person who performed the quality control procedures;~~

~~(x) date of preparation;~~

~~(xi) assigned control, if for anticipation of use or prescription number, if patient specific, whichever is applicable;~~

~~(xii) duplicate label as described in the Master Formulation Record means the sample labeling information that is dispensed on the final product given to the patient and shall at minimum contain:~~

- ~~(A) active ingredients;~~
- ~~(B) beyond use date;~~
- ~~(C) storage conditions; and~~
- ~~(D) lot number;~~
- ~~(xiv) proof of the duplicate labeling information, which proof shall:~~

- ~~(A) be kept at the pharmacy;~~
- ~~(B) be immediately retrievable;~~
- ~~(C) include an audit trail for any altered form; and~~
- ~~(D) be reproduced in:~~
 - ~~(I) the original format that was dispensed;~~
 - ~~(II) an electronic format; or~~
 - ~~(III) a scanned electronic version;~~
- ~~(xvii) description of final preparation;~~

~~_____ (xviii) results of quality control procedures (e.g. weight range of filled capsules, pH of aqueous liquids); and~~

~~_____ (xix) documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver.~~

~~_____ (g) The label of each batch prepared of sterile or non-sterile pharmaceuticals shall bear at a minimum:~~

~~_____ (i) the unique lot number assigned to the batch;~~

~~_____ (ii) all active solution and ingredient names, amounts, strengths and concentrations, when applicable;~~

~~_____ (iii) quantity;~~

~~_____ (iv) beyond use date and time, when applicable;~~

~~_____ (v) appropriate ancillary instructions, such as storage instructions or cautionary statements, including cytotoxic warning labels where appropriate; and~~

~~_____ (vi) device specific instructions, where appropriate.~~

~~_____ (h) All prescription labels for compounded sterile and non-sterile medications when dispensed to the ultimate user or agent shall bear at a minimum in addition to what is required in Section 58-17b-602 the following:~~

~~_____ (i) generic name and quantity or concentration of each active ingredient. In the instance of a sterile preparation for parenteral use, labeling shall include the name and base solution for infusion preparation;~~

~~_____ (ii) assigned compounding record or lot number; and~~

~~_____ (iii) "this is a compounded preparation" or similar language.~~

~~_____ (i) The beyond use date assigned shall be based on currently available drug stability information and sterility considerations or appropriate in-house or contract service stability testing;~~

~~_____ (i) sources of drug stability information shall include the following:~~

~~_____ (A) references can be found in Trissel's "Handbook on Injectable Drugs", 17th Edition, October 31, 2012;~~

~~_____ (B) manufacturer recommendations; and~~

~~_____ (C) reliable, published research;~~

~~_____ (ii) when interpreting published drug stability information, the pharmacist or DMP shall consider all aspects of the final sterile product being prepared such as drug reservoir, drug concentration and storage conditions; and~~

~~_____ (iii) methods for establishing beyond use dates shall be documented; and~~

~~_____ (j) There shall be a documented, ongoing quality control program that monitors and evaluates personnel performance, equipment and facilities that follows the USP-NF Chapters 795 and 797 standards.]~~

(4) The facility shall have current and retrievable editions of the following reference publications in print or electronic format and readily available and retrievable to facility personnel:

(a) Title 58, Chapter 1, Division of Occupational and Professional Licensing Act;

(b) R156-1, General Rule of the Division of Occupational and Professional Licensing;

(c) Title 58, Chapter 17b, Pharmacy Practice Act;

(d) R156-17b, Utah Pharmacy Practice Act Rule;
(e) Title 58, Chapter 37, Utah Controlled Substances Act;
(f) 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) Code of Federal Regulations (CFR) 21, Food and Drugs, Part 1300 to end or equivalent such as the USP DI Drug Reference Guides;
(j) current FDA Approved Drug Products (orange book); and
(k) any other general drug references necessary to permit practice dictated by the usual and ordinary scope of practice to be conducted within that facility.

(5) The facility shall maintain a current list of licensed employees involved in the practice of pharmacy at the facility. The list shall include individual licensee names, license classifications, license numbers, and license expiration dates. The list shall be readily retrievable for inspection by the Division and may be maintained in paper or electronic form.

(6) Facilities shall have a counseling area to allow for confidential patient counseling, where applicable.

(7) A pharmacy shall not dispense a prescription drug or device to a patient unless a pharmacist or DMP is physically present and immediately available in the facility.

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

(9) The facility or parent company shall maintain a record for not less than 5 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 shall not be used.

(10) The pharmacy facility shall maintain copy 3 of DEA order form (Form 222) that has been properly dated, initialed and filed and all copies of each unaccepted or defective order form and any attached statements or other documents.

(11) If applicable, a hard copy of the power of attorney authorizing a pharmacist, DMP, or DMP designee to sign DEA order forms (Form 222) shall be available to the Division whenever necessary.

(12) 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.

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

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

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

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

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

(1) (a) These operating standards shall apply to any person, including any practitioner or facility, who engages in compounding within Utah.

(b) These operating standards shall apply to compounding of all sterile or nonsterile compounded pharmaceuticals, antineoplastic drugs, or non-antineoplastic drugs notwithstanding the location of the patient, including in any hospital, nursing home, assisted living facility, hospice, doctor's office, veterinary facility, or any transitory location.

(c) In addition to the definition of "compounding" in Subsection 58-17b-102(18)(b), "compounding" does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling [21 USC 353a (e)].

(2) 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.

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

In accordance with Subsections 58-17b-102(58), 58-17b-601(1), 58-17b-612(1)(b), and 58-1-301(3), the following operating standards shall apply to a remote dispensing pharmacy:

Commented [1]:

(1) 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).

(2) A remote dispensing pharmacy may not perform compounding.

(3) (a) The supervising pharmacy's PIC shall serve as the remote dispensing pharmacy's RDPIC, who is responsible for all 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.

(4) The Division in collaboration with the Board shall review each application for designation of a remote dispensing pharmacy, and grant approval based upon consideration of the totality of conditions and circumstances demonstrated by the application. The application shall be submitted by the proposed supervising pharmacy on a completed form furnished by the Division [~~that includes:~~

~~(a) complete identifying information concerning the proposed supervising pharmacy;~~

~~(b) complete identifying information concerning the proposed RDPIC;~~

~~(c) the proposed address of the remote dispensing pharmacy, with a detailed description of how that location is in an area of need as defined in Subsection R156-17b-102(4);~~

~~(d) a description of the physical facilities in which the remote dispensing pharmacy will operate;~~

~~(e) a description of the availability of sufficient qualified licensed pharmacy technicians to staff the remote dispensing pharmacy;~~

~~(f) a description of the telepharmacy system that will be used for supervision and counseling; and~~

~~(g) a copy of the proposed policies and procedures manual for the remote dispensing pharmacy and supervising pharmacy, which shall include:~~

~~(i) protecting the confidentiality and integrity of patient information;~~

~~(ii) the conditions under which prescription drugs shall be stored, used, and accounted for;~~

~~(iii) maintaining records to identify the name(s), initial(s), or identification code(s) and specific activities of each pharmacist and pharmacy technician involved in the dispensing process;~~

~~(iv) complying with federal and state law and regulations;~~

~~(v) operation of a 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;~~

~~(vi) annually reviewing the written policies and procedures and documenting such review;~~

~~(vii) requiring monthly in-person inspections of the remote dispensing pharmacy and appropriate documentation by the RDPIC; and~~
~~(viii) any additional policies and procedures required by Subsection R156-17b-614f(2) for Central Prescription Processing].~~

(5) If more than one licensed pharmacy applies for designation of a remote dispensing pharmacy at a similar undesignated location, the Division in collaboration with the Board shall review all of the applications for designation, and if the location is approved, shall approve for licensure the applicant that the Division in collaboration with the Board determines is best able to serve the public interest as identified in this Section.

Commented [2]:

(6) Staffing and Supervision.

(a) At all times that a remote dispensing pharmacy is open and available to serve patients, pharmacy technicians shall remain under the physical supervision or electronic supervision of a supervising pharmacist, as defined in Subsection 58-17b-102(70), from the supervising pharmacy.

~~(b) In accordance with Subsections 58-17b-612(1)(b) and (d) [:(i)] a supervising pharmacist may [not supervise more than] oversee the operation of up to two remote dispensing pharmacies simultaneously [:(and~~

~~(ii) 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].~~

~~(b)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.~~

~~(c) At all times that a remote dispensing pharmacy is open and available to serve patients, all pharmacy technicians shall remain under the physical supervision or electronic supervision of a supervising pharmacist from the supervising pharmacy.]~~

~~(d)e) Adequate supervision by a supervising 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. This supervision may not be delegated to any other person.~~

(7) 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:

- (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).

(8) Each component of the telepharmacy system shall be in good working order. If any 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.

(9) 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:

(a) 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. A supervising 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.

(b) 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.

(10) Facility.

(a) The remote dispensing pharmacy's security system shall allow for tracking of entries into the remote dispensing pharmacy, and 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:

- (A) that the pharmacy is a remote dispensing pharmacy;
- (B) the location of the supervising pharmacy; and
- (C) that at the patient's request, a pharmacist will counsel the patient using audio and video communication systems.

(11) Records and Inspections.

(a) (i) The supervising pharmacy shall maintain records of all 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) The RDPIC shall oversee documented monthly inspections of the remote dispensing pharmacy. Documentation of such inspections shall be kept for five years, and shall include:

- (i) maintenance and reconciliation of all controlled substances;

- (ii) a perpetual inventory of Schedule II controlled substances;
- (iii) temperature logs of the refrigerator and freezer that hold medications; and
- (iv) the RDPIC's periodic review of the record of entries into the remote dispensing pharmacy.

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