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) "ASHP" means the American Society of Health System Pharmacists.
(5) "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.
(6) "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.
(7) "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.
(8) "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.
(9) "Co-licensed partner" means a person that has the right to engage in the manufacturing or marketing of a co-licensed product.
(10) "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.
(11) "Community pharmacy" as used in Subsection 58-17b-625(3)(b) means a class A pharmacy as defined in Subsection 58-17b-102(10).
(12) "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.
(13) "Counterfeit prescription drug" has the meaning given that term in 21 USC 321(g)(2), including any amendments thereto.
(14) "Counterfeiting" means engaging in activities that create a counterfeit prescription drug.
(15) "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.

(16) "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."
(17) "DMP" means a dispensing medical practitioner licensed under Section 58-17b, Part 8.
(18) "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; 2 (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 (9); (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.
(19) "DMPIC" means a dispensing medical practitioner licensed under Section 58-17b, Part 8 who is designated by a dispensing medical practitioner clinic pharmacy to be responsible for activities of the pharmacy.
(20) "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.
(21) "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.
(22) "Drugs", as used in this rule, means drugs or devices.
(23) "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.
(24) "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.
(25) "Entities under common ownership" means entity assets are held indivisibly rather than in the names of individual members.
(26) "ExCPT", as used in this rule, means the Exam for the Certification of Pharmacy Technicians.
(27) "FDA" means the United States Food and Drug Administration and any successor agency.
(28) "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.
(29) "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.

(30) "Hospice facility pharmacy" means a pharmacy that supplies drugs to patients in a licensed healthcare facility for terminal patients.
(31) "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.
(32) "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".
(33) "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.
(34) "Maintenance medications" means medications the patient takes on an ongoing basis.
(35) "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".
(36) "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.
(37) "MPJE" means the Multistate Pharmacy Jurisprudence Examination.
(38) "NABP" means the National Association of Boards of Pharmacy.
(39) "NAPLEX" means North American Pharmacy Licensing Examination.
(40) "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.
(41) "Normal distribution channel" means a chain of custody for a prescription drug that goes directly, by drop shipment as defined in Subsection (19), 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.
(42) "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).
(43) "Parenteral" means a method of drug delivery injected into body tissues but not via the gastrointestinal tract.

(44) "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.
(45) "Pedigree" means a document or electronic file containing information that records each distribution of any given prescription drug.
(46) "PIC", as used in this rule, means the pharmacist-in-charge.
(47)-"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.
(48) "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.
(49) "PTCB" means the Pharmacy Technician Certification Board.
(50)"Qualified continuing education", as used in this rule, means continuing education that meets the standards set forth in Section R156-17b-309.
~~(51) "Refill" means to fill again~~.
(52) "RDPIC" means the PIC of the remote dispensing pharmacy. The RDPIC must be the PIC of the Supervising pharmacy
(53) "Refill" means to fill again.
(54)~~(53)~~ "Remote Dispensing Pharmacy" means the location where the Practice of Pharmacy by in-state licensed Pharmacies and Pharmacists through the use of Telepharmacy Technologies between a licensee and patients occurs. The Practice of Telepharmacy is deemed to occur within the jurisdiction in which the patient is located and the jurisdiction(s) in which the pharmacist is located.

(55)~~(52)~~ "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.
(56)~~(53)~~ "Research facility" means a facility where research takes place that has policies and procedures describing such research.
(57) "Retail Pharmacy" means a pharmaceutical facility that dispenses prescription drugs and devices to the general public, but can also dispense by mailing or shipping.
(58)~~(54)~~ "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.
(59)(55) "Sterile products preparation facility" means any facility, or portion of the facility, that compounds sterile products using aseptic technique.
(60)~~(59)~~ "Supervising Pharmacist" means any pharmacist located at a supervising pharmacy ~~the PIC of the Supervising Pharmacy~~ that supervises ~~oversees~~ the Remote Dispensing pharmacy ~~Facility~~ through the use of telepharmacy technologies.
(61)~~(60)~~ "Supervising Pharmacy" means ~~the~~ a Class A pharmacy that supervises and oversees a Remote Dispensing Pharmacy ~~Facility~~ through telepharmacy technologies.
(62)~~(61)~~~~(56)~~ "Supervisor" means a licensed pharmacist or DMP in good standing with the Division.
(63) "Telepharmacy technologies" means a system that monitors the preparation and dispensing of prescription drugs and provides for related drug review and HIPAA-compliant patient counseling services by an electronic method which shall include the use of the following types of technology:

(1) audio and video;

(2) still image capture; and
(3) store and forward.

(64)~~(62)(57)~~ "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.

(65)~~(58)~~ "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.
(66)~~(59)~~ "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.
(67)~~(60)~~ "Unprofessional conduct", as defined in Title 58, Chapters 1 and 17b, is further defined, in accordance with Subsection 4 58-1-203(1)(e), in Section R156-17b-502.
(68)~~(61)~~ "USP-NF" means the United States Pharmacopeia-National Formulary (USP 40-NF 35), either First Supplement, dated August 1, 2017, or Second Supplement, dated December 1, 2017, which is hereby adopted and incorporated by reference.
(69)~~(62)~~ "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.
(70)~~(63)~~ "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-302. Pharmacy Licensure Classifications – Pharmacist-in-Charge or Dispensing Medical Practitioner-In-Charge Requirements.
In accordance with Subsection 58-17b-302(4), the classification of pharmacies holding licenses are clarified as:
(1) A Class A pharmacy includes all retail operations located in Utah. All Class A pharmacies require a PIC except for remote dispensing pharmacy, (which require a RDPIC). Examples of Class A pharmacies include:
(a) retail pharmacies;
(b) mail order pharmacies;

(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 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; 5 (d) nuclear pharmacies; (e) branch pharmacies; (f) hospice facility pharmacies; (g) pharmaceutical administration facility pharmacies; (h) sterile product preparation facility pharmacies; and (i) dispensing medical practitioner clinic 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 order 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) All pharmacy licenses shall be converted to the appropriate classification by the Division as identified in Section 58-17b302.
(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 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.
(8) A PIC or DMPIC shall comply with the provisions of Section R156-17b-603.

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:
…
(88) failing to comply with the operating standards for a Remote Dispensing Pharmacy as established in Section R156-17b-614g, in violation of Subsection R156-17b-502(26):
Initial offense: $500 - $2,000
Subsequent offense(s): $2,000 - $10,000

R156-17b-502. Unprofessional Conduct.
“Unprofessional conduct” includes:
…
(25) failing to make a timely report regarding dispensing of an opiate antagonist to the Division and to the physician who issued the standing order as required in Section R156-17b-625; and
(26) failing to comply with the operating standards for a Remote Dispensing Pharmacy as established in Section R156-17b-614g.

R156-17b-605. Operating Standards – Inventory Requirements.
(1) All out of date legend drugs and controlled substances shall be removed 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 PIC, DMPIC, or RDPIC shall be responsible for taking all 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 all stocks 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. An inventory taken by use of a verbal recording device shall be promptly transcribed;

(e) the inventory may be taken either as the opening of the business or the close of business on the inventory date;

(f) the person taking the inventory and the PIC, DMPIC, or RDPIC shall indicate the time the inventory was taken and shall sign and date the inventory with the date the inventory was taken. The signature of the PIC, DMPIC, or RDPIC 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;

(g) the person taking the inventory shall make an exact count or measure all controlled substances listed in Schedule I or II;

(h) the person taking the inventory shall make an estimated count or measure of all 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;

(i) the inventory of Schedule I and II controlled substances shall be listed separately from the inventory of Schedule III, IV and V controlled substances;

(j) if the pharmacy maintains a perpetual inventory of any of the drugs required to be inventories, 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) all pharmacies having any stock of controlled substances shall take an inventory on the opening day of business. Such inventory shall include all controlled substances including any out-of-date drugs and drugs in automated pharmacy systems;

(b) in the event a pharmacy commences business with no controlled substances on hand, the pharmacy shall record this fact as the initial inventory. An inventory reporting no Schedule I and II controlled substances shall be listed 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 all 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 all 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, for the purpose of this section, 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 forms (Form 222).

(6) Requirement for taking inventory when closing a pharmacy includes the PIC, DMPIC, RDPIC, owner, or the legal representative of a pharmacy that ceases to operate as a pharmacy shall forward to the Division, within ten days of cessation of operation, a statement attesting that an inventory has been conducted, the date of closing and a statement attesting the manner by which legend drugs and controlled substances possessed by the pharmacy were transferred or disposed.

(7) All pharmacies shall maintain a perpetual inventory of all Schedule II controlled substances that shall be reconciled according to facility policy.

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) 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.

(2) A pharmacy facility shall orally offer to counsel but shall not be required to counsel a patient or patient's agent when the patient or patient's agent 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 and said documentation shall be available to the Division. These records shall be maintained for a period of five years and be available for inspection within 7-10 business days.

(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 the patient's agent at the patient's or other designated location, the following is applicable:

(a) the information specified in Subsection (3) of this section 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) written information provided in Subsection (6)(b) of this section shall be in the form of patient information leaflets similar to USP-NF patient information monographs or equivalent information.

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

(8) The information in Subsection (3) of this section may be provided by a pharmacist through Telepharmacy technologies in a Remote Dispensing Pharmacy.

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

In accordance with Subsections 58-17b-102(58), 58-17b601(1), 58-17b-612(1), and 58-1-301(3), the qualifications for designations as a Remote Dispensing Pharmacy and operating standards include the following:

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

(a) The proposed location of the Remote Dispensing Pharmacy. The pharmacy must be located in:

(i) a remote rural hospital, as defined in Section 26-21-13.6;

(ii) a clinic located in a remote rural county with less than 20 people per square mile; or

(ii) any area where a demonstration of need is approved by the board.

(b) Other factors affecting access of persons in the area to alternative pharmacy resources;

(c) the availability at the location of a qualified certified pharmacy technician to staff the pharmacy;

(d) the availability and willingness of a RDPIC, supervising pharmacy and supervising pharmacist to assume responsibility for the remote dispensing pharmacy;

(e) the availability of physical facilities in which the remote dispensing pharmacy may operate;

(f) a telepharmacy system in place for supervision and counseling; and

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

(2) A Class A pharmacy may be designated as the Supervising Pharmacy and the PIC of the Supervising Pharmacy shall be the RDPIC for the Remote Dispensing Pharmacy, who shall be responsible for all operations of the Remote Dispensing Pharmacy.

(3) A supervising pharmacist can provide pharmacy services for no more than one Remote Dispensing Pharmacy, unless otherwise approved by the Division and the Board.

(4) The application for designation of a Remote Dispensing Pharmacy shall be submitted by the licensed Supervising Pharmacy seeking such designation. In the event that more than one licensed pharmacy makes an application for designation of a Remote Dispensing Pharmacy at a previously undesignated location, the Division in collaboration with the Board shall review all applications for designation of the remote dispensing 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).

(5) An application for a remote dispensing pharmacy shall include the following:

(a) Complete identifying information concerning the applying Supervising Pharmacy;

(b) complete identifying information concerning the RDPIC;

(c) address and description of the facility in which the Remote Dispensing Pharmacy is to be located; and

(d) policy and procedures manual, which includes polices for:

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

(ii) the conditions under which prescription drugs will be store, 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) operating 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 remote dispensing pharmacy and appropriate documentation by supervising pharmacist;

(viii) policy and procedures required in Section R156-17b-614f(2)(a-e) for Central Prescription Processing.

(6) The RDPIC shall oversee documented monthly inspections of the remote dispensing pharmacy. Documentation of such inspections must be kept for five years and shall include:

(a) maintenance and reconciliation of all controlled substances;

(b) maintaining a perpetual inventory of Schedule II controlled substances; and

(c) review of temperature logs of the fridge and freezer which hold medications.

(7) A Supervising Pharmacist shall be available onsite at the remote dispensing pharmacy within two (2) hours, in case of emergency.~~.~~ A 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 provided by the remote dispensing pharmacy in case of an emergency interruption of the remote dispensing pharmacy's services. The plan shall address the timely arrival at the remote dispensing pharmacy of necessary personnel or the delivery to the remote dispensing pharmacy of necessary supplies within a reasonable period of time following the identification of an emergency need. The plan may provide for alternate methods of continuation of the services of the remote dispensing pharmacy including, but not limited to, personal delivery of patient prescription medications from an alternate pharmacy location or on-site pharmacist staffing at the remote dispensing pharmacy.

(8) Unless a pharmacist is physically present, a remote dispensing pharmacy may be staffed by up to two (2) licensed pharmacy technicians with at least two thousand (2,000) hours pharmacy technician experience. All pharmacy technicians must remain under the supervision of a pharmacist at the supervising pharmacy at all times that the remote dispensing pharmacy is open and available to serve patients. Supervision does not require the pharmacist to be physically present at the remote dispensing pharmacy, but the pharmacist must supervise the remote dispensing pharmacy operations electronically from the supervising pharmacy.

(9) Employees may not access a remote dispensing pharmacy during times the supervising pharmacy is closed. The security system must allow for tracking of entries into the remote dispensing pharmacy, and the RDPIC shall periodically review the record of entries.

(10) A Supervising Pharmacy shall maintain records of all orders entered into their information system, including orders entered from a remote dispensing pharmacy. Electronic records must be available to and accessible from both the remote dispensing pharmacy and the supervising pharmacy. Original records of controlled substance prescriptions dispensed from a remote dispensing pharmacy must be maintained at the remote dispensing pharmacy.
(11) A Supervising Pharmacy of a Remote Dispensing Pharmacy must maintain a video and audio communication system that provides for effective communication between the supervising pharmacy and the remote dispensing pharmacy personnel and patients or patient's agent. The system must provide an adequate number of views of the entire site, facilitate adequate pharmacist supervision, and allow the appropriate exchanges of visual, verbal, and written communication for patient counseling and other matters involved in the lawful transaction or dispensing of drugs. The Remote Dispensing Pharmacy must retain a recording of surveillance, excluding patient communications, for a minimum of 90 days.
(12) Adequate supervision by a supervising pharmacist in this setting is maintaining uninterrupted visual supervision and auditory communication with the site and full supervisory control of the automated system, if applicable, and must not be delegated to another person or entity.
(13) Each component of the communication system must be in good working order. Unless a pharmacist is present onsite, the remote dispensing pharmacy shall be, or remain, closed to the public if any component of the communication system is malfunctioning, until system corrections or repairs are completed.
(14) The video and audio communication system used to counsel and interact with each patient or patient's agent must be secure and HIPAA compliant.
(15) The Remote Dispensing Pharmacy must use telepharmacy technology that confirms that the drug selected to fill the prescription is the same as indicated on the prescription label and prescription.
(16) A Remote Dispensing Pharmacy must display a sign, easily visible to the public that informs patients:

(a) this is a Remote Dispensing Pharmacy;
(b) the location of the Supervising Pharmacy; and
(c) that a pharmacist will counsel the patient using audio and video communication systems each upon the patients request at the remote dispensing pharmacy.

(17) If a Remote Dispensing Pharmacy is in a rural area and a Retail Pharmacy is licensed within 10 miles of the Remote Dispensing Pharmacy the license shall not be renewed.

R156-17b-615. Operating Standards - Class C Pharmacy - Pharmaceutical Wholesaler/Distributor and Pharmaceutical Manufacturer.
(19) A Class C pharmacy shall not be located in the same building as a separately licensed Class A, B, D, or E pharmacy (with the exception of a third-party logistic provider) unless the two pharmacies are located in different suites as recognized by the United States Postal Service. Two Class C pharmacies may be located at the same address in the same suite if the pharmacies: (a) are under the same ownership; (b) have processes and systems for separating and securing all aspects of the operation; and (c) have traceability with a clear audit trail that distinguishes a pharmacy's purchases and distributions.

R16-17b-907f Third Party Logistic Provider Operating Standards
(1)A third party logistic provider must comply with storage practices for facilitating including
(a) maintaining access to warehouse space of suitable size to facilitate safe operations, including a suitable area to quarantine suspect product;
(b) maintaining adequate security; and
(c) having 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 repackager or destroyed;
(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) prohibit a facility from having as a manager or designated representative anyone convicted of any felony violation relating to product tampering