**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) "Centralized Prescription Filling" means the filling by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order.~~

~~(8) "Centralized Prescription Processing" means the processing by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order or to perform processing functions such as dispensing, drug utilization review (DUR), claims adjudication, refill authorizations, and therapeutic interventions.]~~

(9) "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.

(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) "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;

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

(34) "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".

(35) "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.

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

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

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

(\_\_) *“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*

(39) "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.

(40) "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).

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

(42) "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.

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

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

(45) "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.

(46) "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.

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

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

(49) "Refill" means to fill again.

(50) "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.

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

(52) "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.

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

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

(55) "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. Such third party logistics provider shall be licensed as a *class E pharmacy* [~~pharmaceutical wholesaler~~] under this chapter and be an "authorized distributor of record" to be considered part of the "normal distribution channel".

(56) "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.

(57) "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.

(58) "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.

(59) "USP-NF" means the United States Pharmacopeia-National Formulary (USP 39-NF 34), 2016 edition, which is official from May 1, 2016 through Supplement 2, dated December 1, 2015, which is hereby adopted and incorporated by reference.

(60) "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.

(61) "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 and requires a PIC.

(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 methadone clinics. Examples of Class B pharmacies include:

(a) closed door pharmacies;

(b) hospital clinic pharmacies;

(c) methadone clinic pharmacies;

(d) nuclear pharmacies;

(e) branch pharmacies;

(f) hospice facility pharmacies;

(g) [~~veterinarian pharmaceutical facility pharmacies~~;]

(h) pharmaceutical administration facility pharmacies;

(i) sterile product preparation facility pharmacies; and

(j) 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; [~~and~~]

(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 58-17b-302.

(7) Each Class A and each Class B pharmacy required to have a PIC or DMPIC shall have one PIC or DMPIC who is employed on a full-time basis as defined by the employer, who acts as a PIC or DMPIC for one pharmacy. However, the PIC or DMPIC 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-304. Temporary Licensure.**

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

(a) is a graduate of an ACPE accredited pharmacy school within two months immediately preceding application for licensure, [~~or~~] enrolled in a pharmacy graduate residency or fellowship program, [~~;]~~ or licensed, in good standing, to practice pharmacy in another state or territory of the United States.

(b) submit a complete application for licensure as a pharmacist except the passing of the NAPLEX and MJPE examinations;

(c) submits evidence of having secured employment conditioned upon issuance of the temporary license, and the employment is under the direct, on-site supervision of a pharmacist with an active, non-temporary license that may or may not include a controlled substance license; and

(d) has registered to take the required licensure examinations.

(2) A temporary pharmacist license issued under Subsection (1) expires the earlier of:

(a) six months from the date of issuance;

(b) the date upon which the Division receives notice from the examination agency that the individual has failed either examination twice; or

(c) the date upon which the Division issues the individual full licensure.

(3) An individual who has failed either examination twice shall meet with the Board to request an additional authorization to test. The Division, in collaboration with the Board, may require additional training as a condition for approval of an authorization to retest.

(4) A pharmacist temporary license issued in accordance with this section cannot be renewed or extended.

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

At least 14 days prior to the closing of a pharmacy, the PIC or DMPIC shall comply with the following:

(1) If the pharmacy is registered to possess controlled substances, send a written notification to the appropriate regional office of the Drug Enforcement Administration (DEA) containing the following information:

(a) the name, address and DEA registration number of the pharmacy;

(b) the anticipated date of closing;

(c) the name, address and DEA registration number of the pharmacy acquiring the controlled substances; and

(d) the date the transfer of controlled substances will occur.

(2) If the pharmacy dispenses prescription drug orders, post a closing notice sign in a conspicuous place in the front of the prescription department and at all public entrance doors to the pharmacy. Such closing notice shall contain the following information:

(a) the date of closing; and

(b) the name, address and telephone number of the pharmacy acquiring the prescription drug orders, including refill information and patient medication records of the pharmacy.

(3) On the date of closing, the PIC or DMPIC shall remove all prescription drugs from the pharmacy by one or a combination of the following methods:

(a) return prescription drugs to manufacturer or supplier for credit or disposal; or

(b) transfer, sell or give away prescription drugs to a person who is legally entitled to possess drugs, such as a hospital or another pharmacy.

(4) If the pharmacy dispenses prescription drug orders:

(a) transfer the prescription drug order files, including refill information and patient medication records, to a licensed pharmacy within a reasonable distance of the closing pharmacy; and

(b) move all signs or notify the landlord or owner of the property that it is unlawful to use the word "pharmacy", or any other word or combination of words of the same or similar meaning, or any graphic representation that would mislead or tend to mislead the public that a pharmacy is located at this address.

(5) Within 10 days of the closing of the pharmacy, the PIC or DMPIC shall forward to the Division a written notice of the closing that includes the following information:

(a) the actual date of closing;

(b) a surrender of the license issued to the pharmacy;

(c) a statement attesting:

(i) that an inventory as specified in Subsection R156-17b-605(4) has been conducted; and

(ii) the manner in which the legend drugs and controlled substances possessed by the pharmacy were transferred or disposed;

(d) if the pharmacy dispenses prescription drug orders, the name and address of the pharmacy to which the prescription drug orders, including refill information and patient medication records, were transferred.

(6) If the pharmacy is registered to possess controlled substances, a letter shall be sent to the appropriate DEA regional office explaining that the pharmacy has closed. The letter shall include the following items:

(a) DEA registration certificate;

(b) all unused DEA order forms (Form 222) with the word "VOID" written on the face of each order form; and

(c) copy #2 of any DEA order forms (Form 222) used to transfer Schedule II controlled substances from the closed pharmacy.

(7) If the pharmacy is closed suddenly due to fire, destruction, natural disaster, death, property seizure, eviction, bankruptcy or other emergency circumstances and the PIC or DMPIC cannot provide notification 14 days prior to the closing, the PIC or DMPIC shall comply with the provisions of Subsection (1) as far in advance of the closing as allowed by the circumstances.

(8) If the PIC or DMPIC is not available to comply with the requirements of this section, the owner or legal representative shall be responsible for compliance with the provisions of this section.

(9) Notwithstanding the requirements of this section, a DMP clinic pharmacy that closes but employs licensed practitioners who desire to continue providing services other than dispensing may continue to use prescription drugs in their practice as authorized under their respective licensing act.

**R156-17b-614f. Operating Standards - ~~Class A, B, D, and E -~~ Central Prescription Processing ~~and Filling.~~**

In accordance with Subsection 58-17b-601(1), the following operating standards apply to ~~Class A, Class B, Class D and Class E~~ pharmacies that engage in central prescription processing as defined in Subsection 58-17b-102 (9) ~~or central prescription filling. The operating standards include~~:

(1) ~~A pharmacy may perform~~ centralized prescription processing ~~or centralized prescription filling~~ services *may be performed* ~~for a dispensing pharmacy~~ if the parties:

(a) have common ownership or common administrative control; or

(b) have a written contract outlining*:*

the services to be provided and

the responsibilities and accountabilities of each party and ~~in fulfilling the terms of said contract~~

~~compliance with federal and state laws and regulations; and~~

(c) share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to fill or refill a prescription drug order.

(2) The parties performing ~~or contracting for~~ *and requesting* centralized prescription processing ~~or filling~~ services shall maintain ~~a~~ policy and procedures manual*s*, and *continual* documentation of implementation, which shall be made available to the Division upon inspection and which includes the following:

(a) a description of how the parties will comply with federal and state laws and regulations;

(b) appropriate records to identify the responsible pharmacists and the dispensing and counseling process;

(c) a mechanism for tracking the prescription drug order during each step in the dispensing process;

(d) a description of adequate security to protect the integrity and prevent the illegal use or disclosure of protected health information; and

(e) a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems.

*(3) “Non-drug or device handling central prescription processing pharmacies”, as defined in Subsection R156-17b-102 ( ) shall be licensed as Class E pharmacy. All other central prescription processing pharmacies shall be licensed in the appropriate pharmacy license classification.*

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

(1) In accordance with Section 58-17b-302 and Subsection 58-17b-601(1), Class E pharmacies shall have a written pharmacy care protocol that includes:

(a) the identity of the supervisor or director;

(b) a detailed plan of care;

(c) the identity of the drugs to be purchased, stored, used and accounted for; and

(d) the identity of any licensed healthcare provider associated with the operation.

[~~(2) A Class E pharmacy preparing sterile compounds shall follow the USP-NF Chapter 797 Compounding for sterile preparations~~]

*(2) Class E pharmacies shall comply with all applicable federal and state laws.*

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

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

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

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

(c) ownership when one of the following occurs:

(i) a change in entity type; or

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

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

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

**R156-17b-618. Change in Location, Name, Entity, and Ownership.**

(1) In accordance with Section 58-17b-614, a licensed pharmaceutical facility shall make application for a new license with the Division no later than ten business days prior to any of the following changes in:

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

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

( ) entity type; or

(c) ownership when the sale or transfer is 51% or more of an entity's direct ownership or membership, except for changes in ownership caused by a change in the stockholders in corporations that are publicly listed and whose stock is publicly traded.

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