State of Utah
Administrative Rule Analysis

NOTICE OF PROPOSED RULE

* The agency identified below in box 1 provides notice of proposed rule change pursuant to Utah Code Section 63G-3-301.
* Please address questions regarding information on this notice to the agency.
* The full text of all rule filings is published in the Utah State Bulletin unless excluded because of space constraints.
* The full text of all rule filings may also be inspected at the Division of Administrative Rules.

DAR file no:	40899	Date filed:	10-20-2016
State Admin Rule Filing Id:		Time filed:	

		Agency No.		Rule No.		Section No.
Utah Admin. Code Ref (R no.):	**R**	156	-	17b	-	
Changed to Admin. Code Ref. (R no.):	**R**		-		-	

1. Agency: Commerce/Division of Occupational and Professional Licensing

Room no.:

Building: Heber M. Wells Building

Street address 1: 160 East 300 South

Street address 2:

City, state, zip: Salt Lake City UT 84111-2316

Mailing address 1: PO Box 146741

Mailing address 2:

City, state, zip: Salt Lake City UT 84114-6741

Contact person(s):

Name:	Phone:	Fax:	E-mail:
Dane Ishihara	801-530-7632	801-530-6511	dishihara@utah.gov

(Interested persons may inspect this filing at the above address or at the Division of Administrative Rules during business hours)

2. Title of rule or section (catchline):

Pharmacy Practice Act Rule

3. Type of notice:

New ___; Amendment XXXX Repeal ___; Repeal and Reenact ___

4. Purpose of the rule or reason for the change:

The Division and Utah State Board of Pharmacy reviewed the rule and determined the following changes are being proposed. This rule filing clarifies the pharmacy license classifications and administrative rules governing central prescription processing pharmacies, third party logistic providers, and veterinarian pharmaceutical facility pharmacies; and amends the name of methadone clinic pharmacies, requirements for closing a pharmacy, temporary pharmacist license requirements and the supervision under which a pharmacy technician trainee can work.

5. This change is a response to comments from the Administrative Rules Review Committee.

No XXXX; Yes ___

6. **Summary of the rule or change:**

Section 102: Paragraphs (7) and (8) are deleted because "central prescription processing" is already defined in Subsection 58-17b-102(9). Paragraph (37) is added to define a "non drug or device handling central prescription processing pharmacy" in rule. Paragraph (54) is modified to change the license classification for third party logistic providers from class C to class E. Paragraph (58) is updated to reflect the most current version of the United States Pharmacopeia-National Formulary (USP-NF) to include Supplement 2, dated December 1, 2016. Section 302: This section is modified to: (1) change the name of methadone clinic pharmacies to narcotic treatment program pharmacies; (2) move veterinarian pharmaceutical facility pharmacies from class B to class E; (3) add non drug or device handling central prescription processing pharmacy to class E; and (4) add third party logistic providers to class E. Section 304: This section is modified to allow individuals licensed and in good standing in another state or territory of the United States to apply for a temporary license in Utah. Section 601: This section is modified to clarify the ratio of pharmacy technician trainee to pharmacist working in a pharmacy at any given time. Section 604: This section is modified to require that pharmacies that are closing surrender their license to the Division. Section 614f: This section is modified to: (1) clarify existing language; (2) establish that non drug handling central prescription processing pharmacies are required to obtain a class E license; and (3) establish that all other central prescription processing pharmacies are required to obtain licensure in the appropriate license classification consistent with their business practices. Section 617a: This section is modified to clearly establish that all class E pharmacies are required to follow all applicable state and federal laws.

7. **Aggregate anticipated cost or savings to:**

A) State budget:

Affected: No ___; Yes XXXX

The Division will incur minimal costs of approximately $75.00 to print and distribute the rule once the proposed amendments are made effective. Any costs incurred will be absorbed in the Division's current budget.

B) Local government:

Affected: No XXX; Yes ___

The proposed amendments apply only to licensees provided in Title 58, Chapter 17b. As a result, the proposed amendments do not apply to local governments.

C) Small businesses ("small business" means a business employing fewer than 50 persons)

Affected: No ___; Yes XXX

The proposed filing primarily adds or modifies definitions and makes clarifications that are consistent with existing practices in the industry. Additionally, affected pharmacies may experience cost savings from the elimination of unnecessary regulation. This includes: (1) defining a "non drug or device handling central prescription processing pharmacy" and "veterinary pharmaceutical facility pharmacies" as class E pharmacies that do not require a pharmacist-in-charge (PIC), where previously these pharmacies were licensed under other classifications that required a PIC; and (2) allowing licensed applicants from out of state to obtain temporary licensure while passing the required examinations for licensure in Utah. The number of businesses affected and the amount of cost savings are unknown and cannot be quantified by the Division due to a wide range of circumstances for each licensee or applicant.

D) Persons other than small businesses, businesses, or local government entities ("person" means any individual, partnership, corporation, association, governmental entity, or public or private organization of any character other than an agency):

Affected: No ___; Yes XXX

Likewise, with regard to large businesses. The proposed filing primarily adds or modifies definitions and makes clarifications that are consistent with existing practices in the industry. Additionally, affected pharmacies may experience cost savings from the elimination of unnecessary regulation. This includes: (1) defining a "non drug or device handling central prescription processing pharmacy" and "veterinary pharmaceutical facility pharmacies" as class E pharmacies that do not require a pharmacist-in-charge (PIC), were previously these pharmacies where licensed under other classifications that required a PIC; and (2) allowing licensed applicants from out of state to obtain temporary licensure while passing the required examinations for licensure in Utah. The number of businesses affected and the amount of cost savings are unknown and cannot be quantified by the Division due to a wide range of circumstances for each licensee or applicant.

8. **Compliance costs for affected persons:**

The proposed filing primarily adds or modifies definitions and makes clarifications that are consistent with existing practices in the industry. Additionally, affected pharmacies may experience cost savings from the elimination of unnecessary regulation. This includes: (1) defining a "non drug or device handling central prescription processing pharmacy" and "veterinary pharmaceutical facility pharmacies" as class E pharmacies that do not require a pharmacist-in-charge (PIC), were previously these pharmacies where licensed under other classifications that required a PIC; and (2) allowing licensed applicants from out of state to obtain temporary licensure while passing the required examinations for licensure in Utah. It is also noted that there is no cost associated with the update to USP 39-NF 34 as Supplement 2, dated December 1, 2016 is included with the yearly subscription price. The number of affected pharmacies and the amount of cost savings are unknown and cannot be quantified by the Division due to a wide range of circumstances for each licensee or applicant.

9. **A) Comments by the department head on the fiscal impact the rule may have on businesses:**

The rule changes primarily add or modify definitions and make clarifications that are consistent with existing practices in the industry. Affected pharmacies may experience cost savings from the elimination of unnecessary regulation. This includes defining a "non drug or device handling central prescription processing pharmacy" and "veterinary pharmaceutical facility pharmacies" as Class E pharmacies that do not require a pharmacist-in-charge (PIC), where previously these pharmacies were licensed under other classifications that required a PIC. Any other fiscal impact is negligible.

B) Name and title of department head commenting on the fiscal impacts:

Francine A. Giani. Executive Director

10. **This rule change is authorized or mandated by state law, and implements or interprets the following state and federal laws.**
State code or constitution citations (required) (e.g., Section 63G-3-402; Subsection 63G-3-601(3); Article IV):

Section 58-17b-101	Subsection 58-17b-601(1)
Section 58-37-1	Subsection 58-1-106(1)(a)
Subsection 58-1-202(1)(a)	

11. **This rule adds, updates, or removes the following title of materials incorporated by references** (a copy of materials incorporated by reference must be submitted to the Division of Administrative Rules; *if none, leave blank*):

	First Incorporation	Second Incorporation
Official Title of Materials Incorporated (from title page)	USP 39-NF 34 through Supplement 2	
Publisher	United States Pharmacopeial Convention	
Date Issued	December 1, 2016	
Issue, or version		
ISBN Number (optional)		
ISSN Number (optional)		
Cost of Incorporated Reference	-0-	
Action: Adds, updates, or removes	Updates	

(If this rule incorporates more than two items by reference, please attach additional pages)

12. **The public may submit written or oral comments to the agency identified in box 1.** (The public may also request a hearing by submitting a written request to the agency. The agency is required to hold a hearing if it receives requests from ten interested persons or from an association having not fewer than ten members. Additionally, the request must be received by the agency not more than 15 days after the publication of this rule in the Utah State Bulletin. See Section 63G-3-302 and Rule R15-1 for more information.)

A) Comments will be accepted until 5:00 p.m. on (mm/dd/yyyy): 12/15/2016

B) A public hearing (optional) will be held:

On (mm/dd/yyyy): **At** (hh:mm AM/PM): **At** (place):

11/15/2016	9:00 AM	160 East 300 South, Conference Room 474 (4th floor), Salt Lake City, Utah

13. This rule change may become effective on (mm/dd/yyyy): 12/22/2016

NOTE: The date above is the date on which this rule MAY become effective. It is NOT the effective date. After the date designated in Box 12(A) above, the agency must submit a Notice of Effective Date to the Division of Administrative Rules to make this rule effective. Failure to submit a Notice of Effective Date will result in this rule lapsing and will require the agency to start the rulemaking process over.

14. Indexing information -- keywords (maximum of four, in lower case, except for acronyms (e.g., "GRAMA") or proper nouns (e.g., "Medicaid"); may not include the name of the agency:

pharmacists licensing

pharmacies

15. Attach an RTF document containing the text of this rule change (filename): R156-17b.pro1

To the agency: Information requested on this form is required by Sections 63G-3-301, 302, 303, and 402. Incomplete forms will be returned to the agency for completion, possibly delaying publication in the *Utah State Bulletin*, and delaying the first possible effective date.

AGENCY AUTHORIZATION

Agency head or designee, and title: **Date** (mm/dd/yyyy): 10/28/2016

R156. Commerce, Occupational and Professional Licensing.
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) "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~~]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.

([~~10~~]8) "Co-licensed partner" means a person that has the right to engage in the manufacturing or marketing of a co-licensed product.

([~~11~~]9) "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~~]10) "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~~]11) "Counterfeit prescription drug" has the meaning given that term in 21 USC 321(g)(2), including any amendments thereto.

([~~14~~]12) "Counterfeiting" means engaging in activities that create a counterfeit prescription drug.

([~~15~~]13) "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~~]14) "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~~]15) "DMP" means a dispensing medical practitioner licensed under Section 58-17b, Part 8.

([~~18~~]16) "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~~]17) "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~~]18) "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~~]19) "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~~]20) "Drugs", as used in this rule, means drugs or devices.

([~~23~~]21) "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~~]22) "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~~]23) "Entities under common ownership" means entity assets are held indivisibly rather than in the names of individual members.

([~~26~~]24) "ExCPT", as used in this rule, means the Exam for the Certification of Pharmacy Technicians.

([~~27~~]25) "FDA" means the United States Food and Drug Administration and any successor agency.

([~~28~~]26) "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~~]27) "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~~]28) "Hospice facility pharmacy" means a pharmacy that supplies drugs to patients in a licensed healthcare facility for terminal patients.

([~~31~~]29) "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~~]30) "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~~]31) "Maintenance medications" means medications the patient takes on an ongoing basis.

([~~34~~]32) "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~~]33) "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~~]34) "MPJE" means the Multistate Jurisprudence Examination.

([~~37~~]35) "NABP" means the National Association of Boards of Pharmacy.

([~~38~~]36) "NAPLEX" means North American Pharmacy Licensing Examination.

(37) "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~~]38) "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~~]39) "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~~]40) "Parenteral" means a method of drug delivery injected into body tissues but not via the gastrointestinal tract.

([~~42~~]41) "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~~]42) "Pedigree" means a document or electronic file containing information that records each distribution of any given prescription drug.

([~~44~~]43) "PIC", as used in this rule, means the pharmacist-in-charge.

([~~45~~]44) "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~~]45) "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~~]46) "PTCB" means the Pharmacy Technician Certification Board.

([~~48~~]47) "Qualified continuing education", as used in this rule, means continuing education that meets the standards set forth in Section R156-17b-309.

([~~49~~]48) "Refill" means to fill again.

([~~50~~]49) "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~~]50) "Research facility" means a facility where research takes place that has policies and procedures describing such research.

([~~52~~]51) "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~~]52) "Sterile products preparation facility" means any facility, or portion of the facility, that compounds sterile products using aseptic technique.

([~~54~~]53) "Supervisor" means a licensed pharmacist or DMP in good standing with the Division.

([~~55~~]54) "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 pharmaceutical wholesaler under this chapter and be an "authorized distributor of record" to be considered part of the "normal distribution channel".~~]

([~~56~~]55) "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~~]56) "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~~]57) "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~~]58) "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~~]2016, which is hereby adopted and incorporated by reference.

([~~60~~]59) "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~~]60) "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~~]narcotic treatment program pharmacies. Examples of Class B pharmacies include:

(a) closed door pharmacies;

(b) hospital clinic pharmacies;

(c) [~~methadone clinic pharmacies~~]narcotic treatment program pharmacies;

(d) nuclear pharmacies;

(e) branch pharmacies;

(f) hospice facility pharmacies;

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

~~(h)~~]pharmaceutical administration facility pharmacies;

([~~i~~]h) sterile product preparation facility pharmacies; and

([~~j~~]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; [~~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 in Utah 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-601. Operating Standards - Pharmacy Technician and Pharmacy Technician Trainee.

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

(1) A pharmacy technician may perform any task associated with the physical preparation and processing of prescription and medication orders including:

(a) receiving written prescriptions;

(b) taking refill orders;

(c) entering and retrieving information into and from a database or patient profile;

(d) preparing labels;

(e) retrieving medications from inventory;

(f) counting and pouring into containers;

(g) placing medications into patient storage containers;

(h) affixing labels;

(i) compounding;

(j) counseling for over-the-counter drugs and dietary supplements under the direction of the supervising pharmacist as referenced in Subsection 58-17b-102(56);

(k) accepting new prescription drug orders left on voicemail for a pharmacist to review;

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

(i) technicians authorized by a hospital to check medications shall have at least one year of experience working as a pharmacy technician and at least six months experience at the hospital where the technician is authorized to check medications;

(ii) technicians shall only check steps in the medication distribution process that do not require the professional judgment of a pharmacist and that are supported by sufficient automation or technology to ensure accuracy (e.g. barcode scanning, drug identification automation, checklists, visual aids);

(iii) hospitals that authorize technicians to check medications shall have a training program and ongoing competency assessment that is documented and retrievable for the duration of each technician's employment and at least three years beyond employment, and shall maintain a list of technicians on staff that are allowed to check medications;

(iv) hospitals that authorize technicians to check medications shall have a medication error reporting system in place and shall be able to produce documentation of its use;

(v) a supervising pharmacist shall be immediately available during all times that a pharmacy technician is checking medications;

(vi) hospitals that authorize technicians to check medications shall have comprehensive policies and procedures that guide technician checking that include the following:

(A) process for technician training and ongoing competency

assessment and documentation;

(B) process for supervising technicians who check medications;

(C) list of medications, or types of medications that may or may not be checked by a technician;

(D) description of the automation or technology to be utilized by the institution to augment the technician check;

(E) process for maintaining a permanent log of the unique initials or identification codes that identify each technician responsible for checked medications by name; and

(F) description of processes used to track and respond to medication errors; and

(m) additional tasks not requiring the judgment of a pharmacist.

(2) A pharmacy technician trainee may perform any task in Subsection (1) with the exception of performing checks of certain medications prepared for distribution filled or prepared by another technician within a Class B hospital pharmacy as described in Subsection (1)(l).

(3) The pharmacy technician shall not receive new prescriptions or medication orders as described in Subsection 58-17b-102(56)(b)(iv), clarify prescriptions or medication orders nor perform drug utilization reviews. A new prescription, as used in Subsection 58-17b-102(56)(b)(iv), does not include authorization of a refill of a legend drug.

(4) Pharmacy technicians shall have general supervision by a pharmacist in accordance with Subsection R156-17b-603(3)(s).

(5) [~~No more than one pharmacy technician trainee per shift shall practice in a pharmacy. A pharmacy technician trainee shall practice only under the direct supervision of a pharmacist.~~]A pharmacy technician trainee shall practice only under the direct supervision of a pharmacist and in a ratio not to exceed one pharmacy technician trainee to one pharmacist.

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 c~~]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 in fulfilling the terms of said contract[~~ in 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 centralized prescription processing [~~or filling~~]services shall maintain a policy and procedures manual, and documentation of implementation, which shall be made available to the Division upon inspection and which includes the following:

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

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

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

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

(e) a continuous quality improvement program for pharmacy

services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems.

(3) "Non drug or device handling central prescription processing pharmacies", as defined in Subsection R156-17b-102(37), shall be licensed as Class E pharmacies. 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~~]Class E pharmacies shall comply with all applicable federal and state laws.

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