Monthly Pharmacy Cases Received

As of 2026-06-08 08:46:36 Mountain Standard Time/MST • Generated by Travis Drebing • Sorted by Opened Date (Ascendir

Filtered By

Date Field: Opened Date equals Last Month (5/1/2026 to 5/31/2026)
Show: All cases
Units: Hours
Status equals Case Received,Under Investigation,Legal Action,Information Only
Conduct Unit equals Healthcare,Professional
Professions equals Pharmacy

Case Number	Opened Date	Professions	Profession Subtype	Complaint Types	Status
171486	5/4/2026	Pharmacy			Information Only
171497	5/5/2026	Pharmacy			Information Only
171550	5/6/2026	Pharmacy	Class A-Retail	Inspection	Under Investigation
171577	5/6/2026	Pharmacy	Pharmacy Technician	Pharmacy Violation	Under Investigation
171670	5/8/2026	Pharmacy	Pharmacist		Information Only
171797	5/13/2026	Pharmacy	Pharmacist		Information Only
171798	5/13/2026	Pharmacy	Class A-Retail		Information Only
171965	5/18/2026	Pharmacy		Pharmacy Violation	Under Investigation
172037	5/20/2026	Pharmacy	Class A-Retail	Pharmacy Violation	Under Investigation
172350	5/29/2026	Pharmacy	Pharmacist		Under Investigation
Total Count	10				

Monthly Pharmacy Closed Cases

As of 2026-06-08 08:45:37 Mountain Standard Time/MST • Generated by Travis Drebing • Sorted by Closed Date (Ascending)

Filtered By
Date Field: Closed Date equals Last Month (5/1/2026 to 5/31/2026)
Show: All cases
Units: Days
Conduct Unit equals Professional,Healthcare
Professions equals Pharmacy

Case Number	Closed Date	Professions	Profession Subtype	Complaint Types	Closure Code	Status
171189	5/6/2026	Pharmacy	Class A-Retail			Information Only
171510	5/6/2026	Pharmacy	Class C-Wholesaler	Pharmacy Violation	Administrative Discretion	Closed
171505	5/6/2026	Pharmacy	Class D-Out of State	Pharmacy Violation	Voluntary Compliance	Closed
171397	5/7/2026	Pharmacy	Class A-Retail	Inspection	Random Inspection; Voluntary Compliance	Closed
171353	5/7/2026	Pharmacy	Class A-Retail	Inspection	Random Inspection; Voluntary Compliance	Closed
171390	5/7/2026	Pharmacy	Class A-Retail	Inspection	Letter of Concern; Random Inspection; Voluntary Compliance	Closed
171589	5/7/2026	Pharmacy	Class A-Retail	Inspection	Random Inspection	Closed
171564	5/7/2026	Pharmacy	Class A-Retail	Inspection	Random Inspection	Closed
171562	5/7/2026	Pharmacy	Class A-Retail	Inspection	Random Inspection; Voluntary Compliance	Closed
171643	5/8/2026	Pharmacy	Class A-Retail	Inspection	Random Inspection	Closed
171644	5/8/2026	Pharmacy	Class A-Retail	Inspection	Letter of Concern; Random Inspection	Closed
171486	5/11/2026	Pharmacy				Information Only
171646	5/11/2026	Pharmacy	Class A-Retail	Inspection	Random Inspection; Voluntary Compliance	Closed
171617	5/11/2026	Pharmacy	Class A-Retail	Inspection	Random Inspection	Closed
171622	5/11/2026	Pharmacy	Class A-Retail	Inspection	Letter of Concern; Random Inspection	Closed
171497	5/11/2026	Pharmacy				Information Only
171759	5/13/2026	Pharmacy	Class A-Retail	Inspection	New Inspection; Voluntary Compliance	Closed
171670	5/13/2026	Pharmacy	Pharmacist			Information Only
171797	5/13/2026	Pharmacy	Pharmacist			Information Only
171782	5/14/2026	Pharmacy	Class A-Retail	Inspection	Random Inspection	Closed
171783	5/14/2026	Pharmacy	Class A-Retail	Inspection	Random Inspection	Closed
171798	5/14/2026	Pharmacy	Class A-Retail			Information Only
171768	5/14/2026	Pharmacy	Class B-Closed Door	Inspection	New Inspection	Closed
171846	5/14/2026	Pharmacy	Class A-Retail	Inspection	Letter of Concern; Random Inspection	Closed
171847	5/14/2026	Pharmacy	Class A-Retail	Inspection	Letter of Concern; Random Inspection	Closed
171852	5/14/2026	Pharmacy	Class A-Retail	Inspection	Random Inspection	Closed
171834	5/15/2026	Pharmacy	Class A-Retail	Inspection	Letter of Concern; Random Inspection	Closed
171823	5/15/2026	Pharmacy	Licensed Dispensing Practice	Inspection	New Inspection	Closed
171854	5/15/2026	Pharmacy	Class A-Retail	Inspection	Random Inspection	Closed
171849	5/18/2026	Pharmacy	Licensed Dispensing Practice	Inspection	New Inspection; Voluntary Compliance	Closed
171703	5/18/2026	Pharmacy	Class A-Retail	Inspection	Letter of Concern; Random Inspection	Closed
171178	5/18/2026	Pharmacy	Class A-Retail	Inspection	Letter of Concern; Random Inspection	Closed
171976	5/19/2026	Pharmacy	Licensed Dispensing Practice	Inspection	Administrative Discretion	Closed
171829	5/19/2026	Pharmacy	Class B-Pharmaceutical Administration Facility	Inspection	New Inspection	Closed
171831	5/19/2026	Pharmacy	Class B-Pharmaceutical Administration Facility	Inspection	New Inspection	Closed
171970	5/19/2026	Pharmacy	Class B-Pharmaceutical Administration Facility	Inspection	Administrative Discretion	Closed
171974	5/19/2026	Pharmacy	Class E-Veterinary Pharmaceutical Facility	Pharmacy Violation	Verbal Warning	Closed
172033	5/21/2026	Pharmacy	Class B-Hospital Clinic	Inspection	Random Inspection	Closed
171881	5/21/2026	Pharmacy	Class A-Retail	Inspection	Random Inspection; Voluntary Compliance	Closed
171698	5/21/2026	Pharmacy	Class A-Retail	Inspection	Letter of Concern; Random Inspection	Closed
172077	5/21/2026	Pharmacy	Class A-Retail	Inspection	Random Inspection	Closed
172052	5/21/2026	Pharmacy	Class B-Hospital Clinic	Inspection	Random Inspection; Voluntary Compliance	Closed
171321	5/22/2026	Pharmacy	Class B-Closed Door	Unprofessional Conduct	Lack of Evidence	Closed
171827	5/29/2026	Pharmacy	Class A-Retail	Inspection	Random Inspection; Voluntary Compliance	Closed
172250	5/29/2026	Pharmacy	Class C-Distributing	Inspection	New Inspection; Voluntary Compliance	Closed
172252	5/29/2026	Pharmacy	Class E-Third Party Logistics Provider	Inspection	New Inspection; Voluntary Compliance	Closed
Total Count	46					

Monthly Pharmacy Inspections

As of 2026-06-08 08:44:12 Mountain Standard Time/MST • Generated by Travis Drebing • Sorted by Inspection Da

Filtered By
Show: All inspections
Date Field: Inspection Date equals Last Month (5/1/2026 to 5/31/2026)
Inspection Type equals New,Probation,Random

Case	Inspection Date	Inspection Classification	Inspection Type
171759	5/5/2026, 12:00 PM	Class A-Retail	New
171562	5/6/2026, 12:00 PM	Class A-Retail	Random
171564	5/6/2026, 12:00 PM	Class A-Retail	Random
171589	5/6/2026, 12:00 PM	Class A-Retail	Random
171617	5/6/2026, 12:00 PM	Class A-Retail	Random
171622	5/6/2026, 12:00 PM	Class A-Retail	Random
171622	5/6/2026, 12:00 PM	Automated Pharmacy System	Random
171643	5/7/2026, 12:00 PM	Class A-Retail	Random
171644	5/7/2026, 12:00 PM	Class A-Retail	Random
171768	5/11/2026, 12:00 PM	Class B-Closed Door	New
171782	5/12/2026, 12:00 PM	Class A-Retail	Random
171783	5/12/2026, 12:00 PM	Class A-Retail	Random
171827	5/12/2026, 12:00 PM	Class A-Retail	Random
171827	5/12/2026, 12:00 PM	Automated Pharmacy System	Random
171846	5/12/2026, 12:00 PM	Class A-Retail	Random
171846	5/12/2026, 12:00 PM	Automated Pharmacy System	Random
171847	5/12/2026, 12:00 PM	Class A-Retail	Random
171852	5/12/2026, 12:00 PM	Class A-Retail	Random
171854	5/12/2026, 12:00 PM	Class A-Retail	Random
171854	5/12/2026, 12:00 PM	Automated Pharmacy System	Random
171829	5/13/2026, 12:00 PM	Sterile Compounding	New
171829	5/13/2026, 12:00 PM	Class B-Pharmaceutical Administration Facility	New
171829	5/13/2026, 12:00 PM	Automated Pharmacy System	New
171831	5/13/2026, 12:00 PM	Class B-Pharmaceutical Administration Facility	New
171831	5/13/2026, 12:00 PM	Automated Pharmacy System	New
171831	5/13/2026, 12:00 PM	Sterile Compounding	New
171834	5/13/2026, 12:00 PM	Class A-Retail	Random
171881	5/14/2026, 12:00 PM	Class A-Retail	Random
172033	5/19/2026, 12:00 PM	Class B-Hospital Clinic	Random
172033	5/19/2026, 12:00 PM	Automated Pharmacy System	Random
172033	5/19/2026, 12:00 PM	Sterile Compounding	Random
172250	5/19/2026, 12:00 PM	Class C-Distributing	New
172252	5/19/2026, 12:00 PM	Class E-Third Party Logistics Provider	New
172052	5/20/2026, 12:00 PM	Class B-Hospital Clinic	Random
172052	5/20/2026, 12:00 PM	Automated Pharmacy System	Random
172052	5/20/2026, 12:00 PM	Sterile Compounding	Random
172077	5/20/2026, 12:00 PM	Class A-Retail	Random
172124	5/21/2026, 12:00 PM	Class A-Retail	Random
172398	5/27/2026, 12:00 PM	Class A-Retail	Random
172401	5/27/2026, 12:00 PM	Class C-Distributing	New
172403	5/27/2026, 12:00 PM	Class A-Retail	Random
172403	5/27/2026, 12:00 PM	Automated Pharmacy System	Random
172411	5/27/2026, 12:00 PM	Class B-Pharmaceutical Administration Facility	Random
172432	5/27/2026, 12:00 PM	Class A-Retail	Random
172407	5/28/2026, 12:00 PM	Class B-Hospital Clinic	Random
172407	5/28/2026, 12:00 PM	Class B-Sterile Product Preparation Facility	Random
172407	5/28/2026, 12:00 PM	Automated Pharmacy System	Random
172418	5/28/2026, 12:00 PM	Class E-Durable Medical Equipment	New
172418	5/28/2026, 12:00 PM	Class E- Medical Gas Provider	New
172419	5/28/2026, 12:00 PM	Class B-Hospital Clinic	Random
172419	5/28/2026, 12:00 PM	Class B-Sterile Product Preparation Facility	Random
172419	5/28/2026, 12:00 PM	Automated Pharmacy System	Random
Total Count	52		

Monthly Pharmacy Citations

As of 2026-06-08 08:43:02 Mountain Standard Time/MST • Generated by Travis Drebing • Sorted by Date Issued (Ascending)

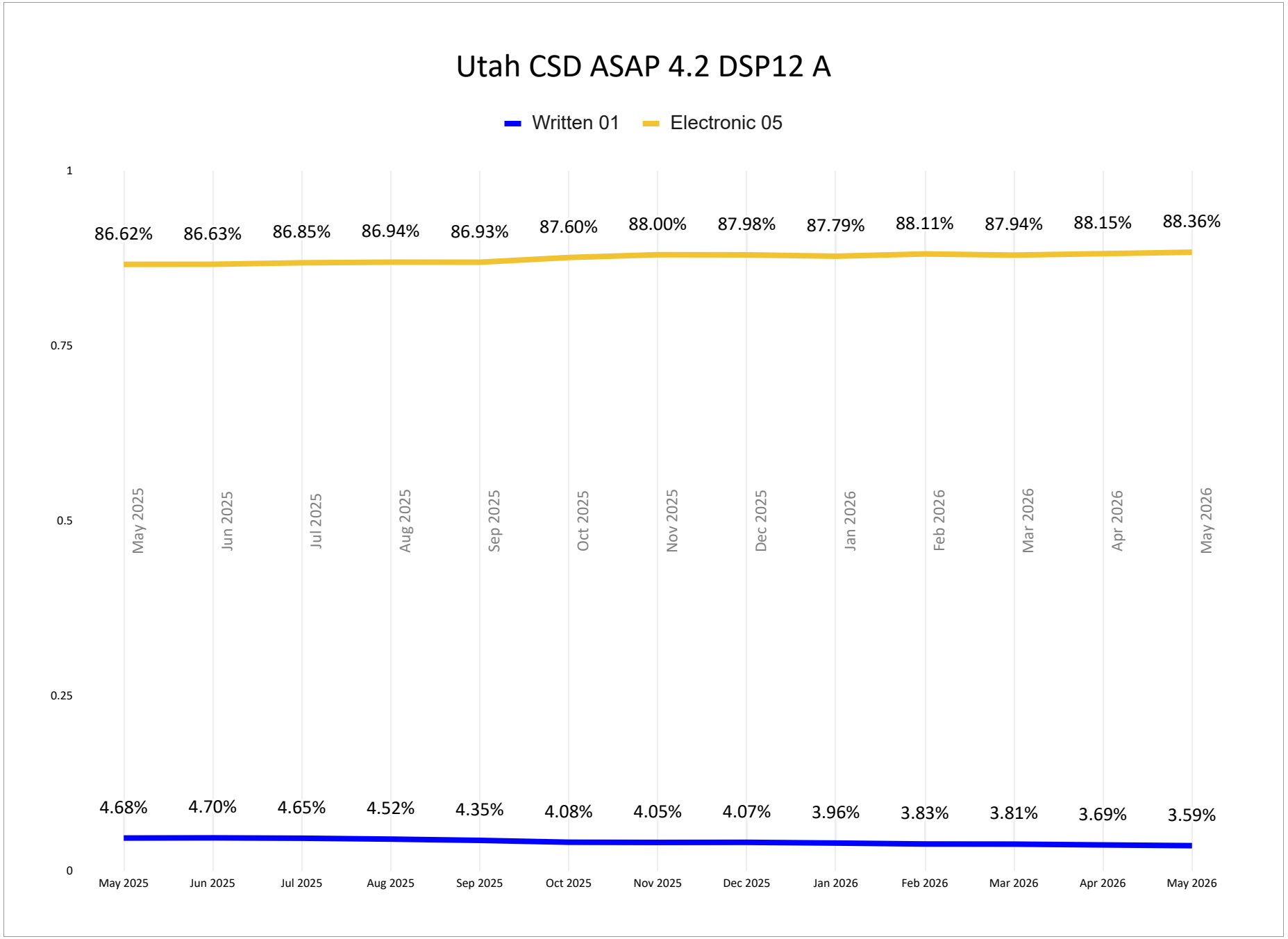
Filtered By

Show: All citations

Date Field: Date Issued equals Last Month (5/1/2026 to 5/31/2026)

Profession equals pharmacy

Date Issued		Case	DOPL Citation: Citation Number	Profession	Violation Type
Total	Count	0			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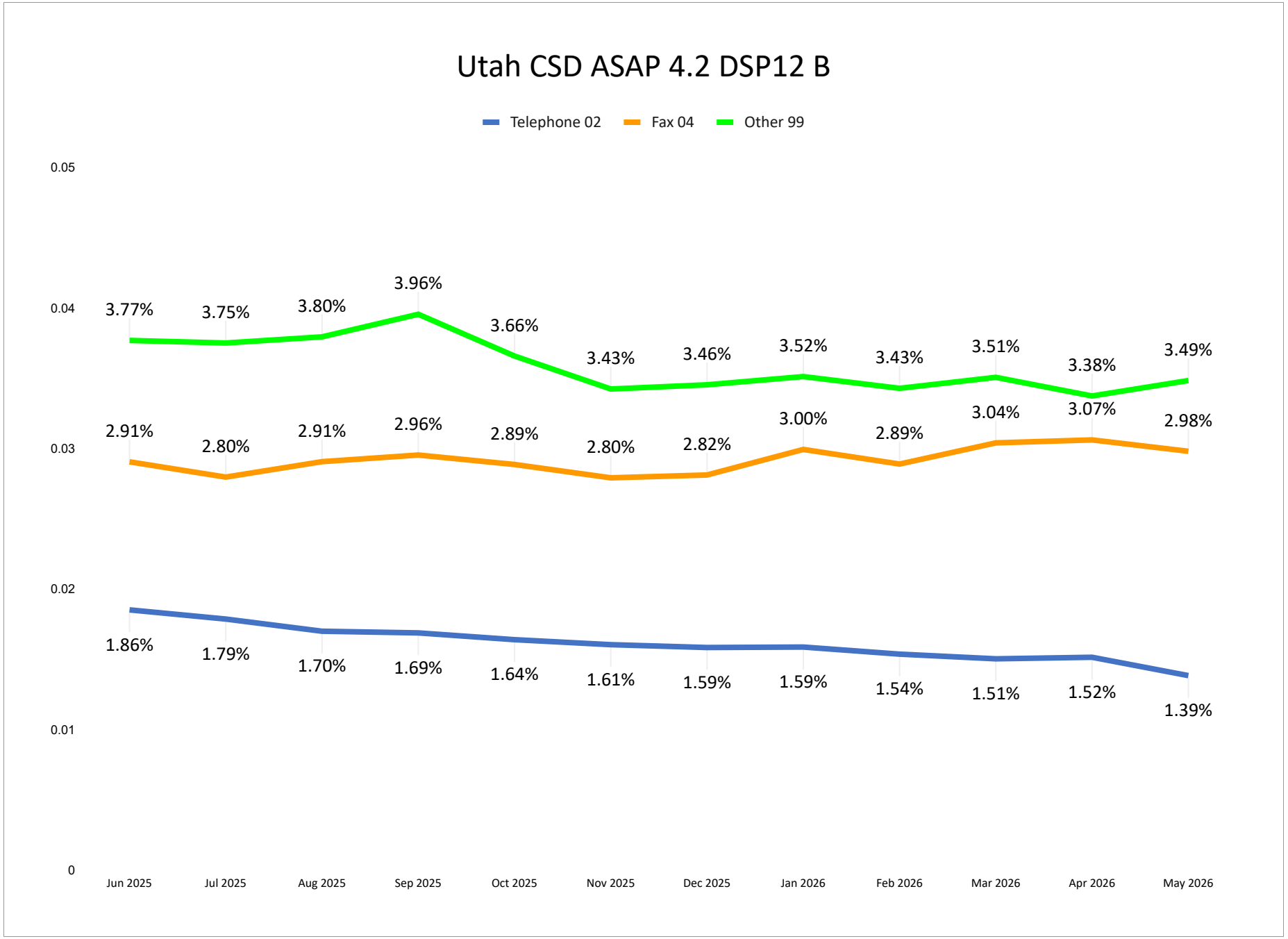
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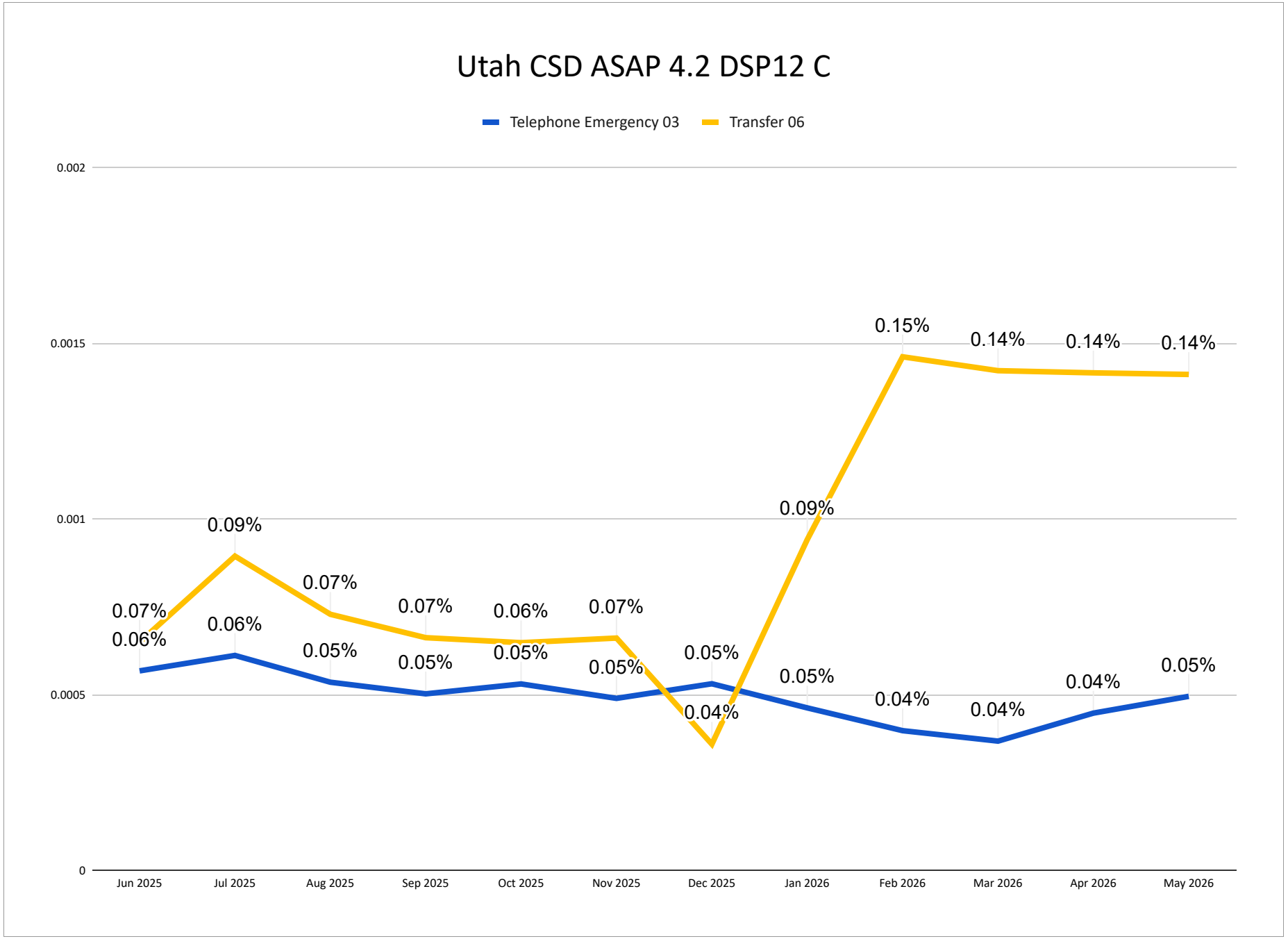
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National Healthcareer Association

PharmaSeer™

Utah Board of Pharmacy
June 2026

YOUR NHA TEAM

Director, Pharmacy + Career Technical Education

Laura Flynn

Partnership Manager

Stacy Abernethy

Purpose & Request

The purpose of this document is to provide the Utah Board of Pharmacy with an overview of PharmaSeer™, a digital learning resource developed by the National Healthcareer Association (NHA).

Specifically, NHA respectfully requests that the Board and the Division consider PharmaSeer™ for acceptance as a didactic training resource that may be used by training providers as part of a Division-approved pharmacy technician training program, consistent with Utah Administrative Code requirements.

This overview is intended to clearly describe:

- The scope and role of PharmaSeer™
- How it aligns with Utah pharmacy technician training requirements
- What PharmaSeer™ does and does not represent from a regulatory standpoint

National Healthcareer Association

National Healthcareer Association

Topics Today

- NHA + PharmaSeer™ Introduction
- The scope and role of PharmaSeer™
- How it aligns with Utah pharmacy technician training requirements
- What PharmaSeer™ does and does not represent from a regulatory standpoint
- Discussion Q+A

Since 1989, NHA has helped developed Job-Ready Allied Health Professionals

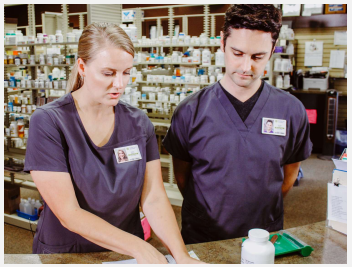
Helping over **2,600 schools** train and credential Allied Health Professionals

Enabling over **800 healthcare employers** to address workforce shortages and improve retention

Guiding over **1.3 million professionals** to effectively transition to the workplace and achieve their full potential

Ultimately driving positive outcomes for patients

Our approach to delivering better outcomes

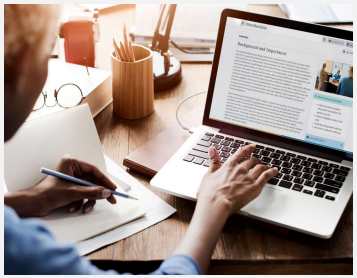


Job-Ready Allied Health Professionals

*"NHA materials, in my opinion, are **more engaging for students** since they use a mix of video and interactive practice drills to help students focus on key concepts. NHA study guides are **some of the best I've seen**."*

Superior Customer Experiences

*"NHA stays up to date and **current with the changes in healthcare**. The customer service is excellent, and I appreciate the **training and information that they give to instructors** when new products come out."*



Actionable Analytics for Better Learner Performance

*"The modules are set up in a fun way for the students to study from and **track their progress**. The practice assessments are great for the student to **see where they excel or need help** with, and the focused review is very beneficial to the student."*

Designed by Experts

National Healthcareer Association

PharmaSeer™

What PharmaSeer Pro™ is...

Competency-Based Skills
20 MODULES

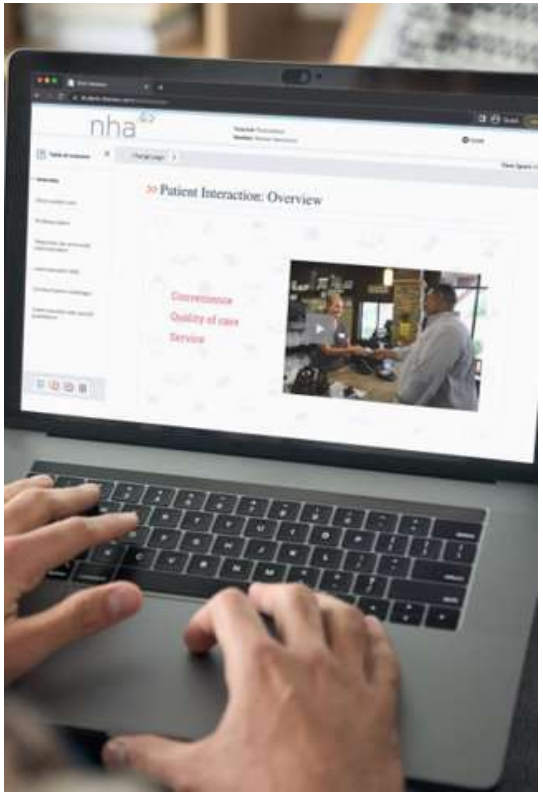
More effective and efficient pharmacy technician training

PharmaSeer™ is a comprehensive, online learning resource intended to serve as the didactic component of a pharmacy technician training

Interactive Learning Experience
Gamification, videos, audio content narration, top 200 medications flashcards, and more

Structured Training
- Guided content recommendations based on each employee's pre-assessment scores
- Appropriate and adaptable to varying levels of experience
- Content aligned to entry-level didactic standards established by the American Society of Health-System Pharmacists (ASHP)

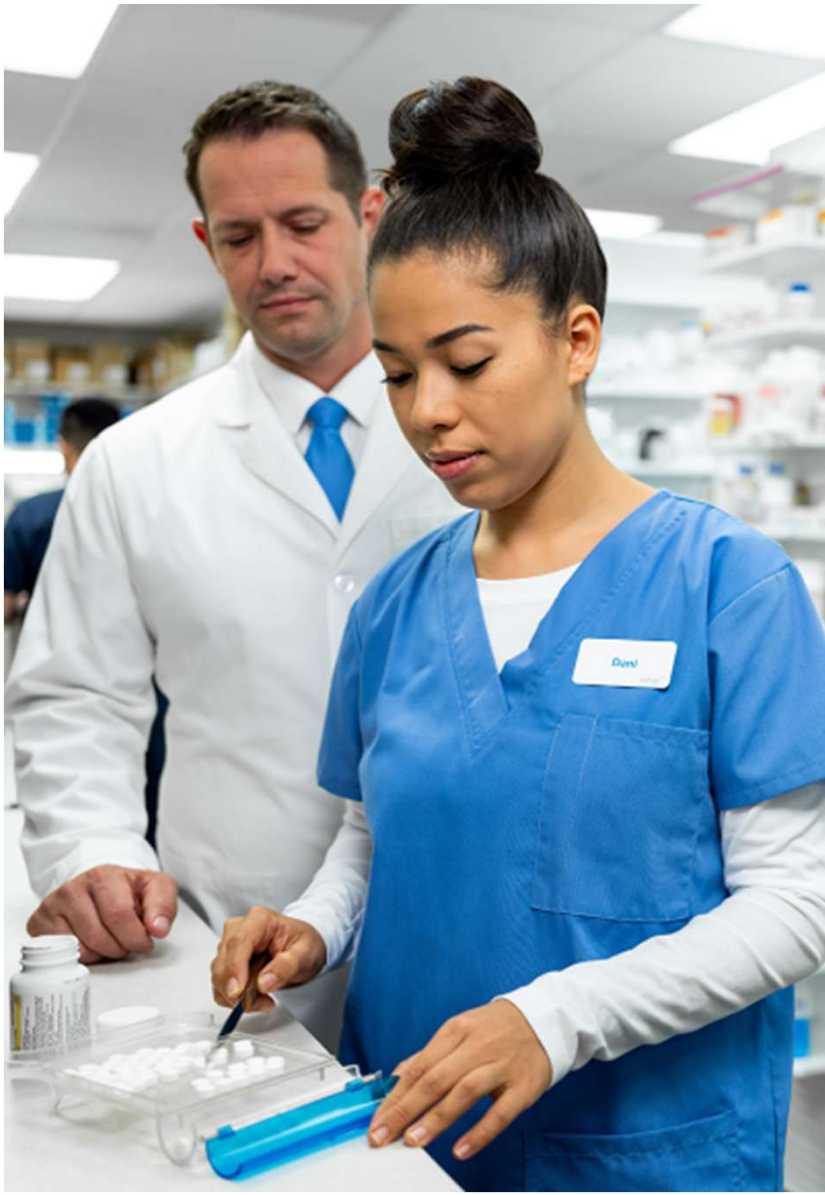
Competency Validation
- Pre and post-assessments
- Quizzes at the end of each lesson and module
- Employee usage and performance analytics



What PharmaSeer™ is NOT…

For clarity and transparency, PharmaSeer™ is not:

- A complete or standalone pharmacy technician training program
- A replacement for **directly supervised practical or experiential training**
- A substitute for training provider responsibilities related to:
  - Supervision
  - Evaluation
  - Documentation
- A Source of state-specific pharmacy laws or employer-specific SOP's



Addressing Today's Challenges Today

Learner challenges:

Complicated subject matter

General learner anxiety around math/calculations[3]

One calculation method doesn't resonate with all learners

Facilitator challenges:

Low learner comprehension based on different needs and styles

Several available resources only educate on 1 learning method

Many don't know where their learners are struggling

Module 1: Introduction and Measurement Basics
Module 2: Dispensing Calculations and Business Math
Module 3: Single-dose Calculations
Module 4: Sterile and Nonsterile Compounding Calculations
Module 5: Calculations for Special Circumstances

View PharmaSeer Resources

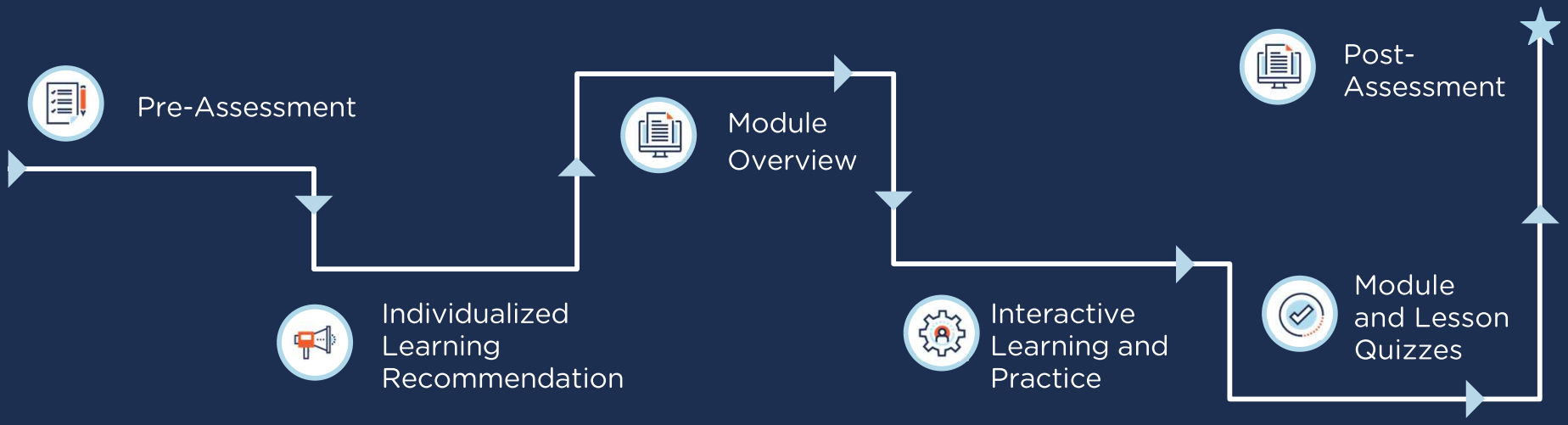
Use this link to Access:

- List of Modules + Lessons
- Industry Mapping and Alignment
  - ASHP, PTCE, ExCPT
- Additional resources

Link to Resources

National Healthcareer Association

PharmaSeer Pro™ works by first assessing the employee's current knowledge and then delivering guided content recommendations based on their competency.



How it Works

Pre-Assessment

- 130 questions
- Allows employees + managers to identify knowledge gaps and help guide learning

Individualized Learning Recommendation

- Pre-assessment score breaks down performance by module to help prioritize learning and streamline training process

Module Overview

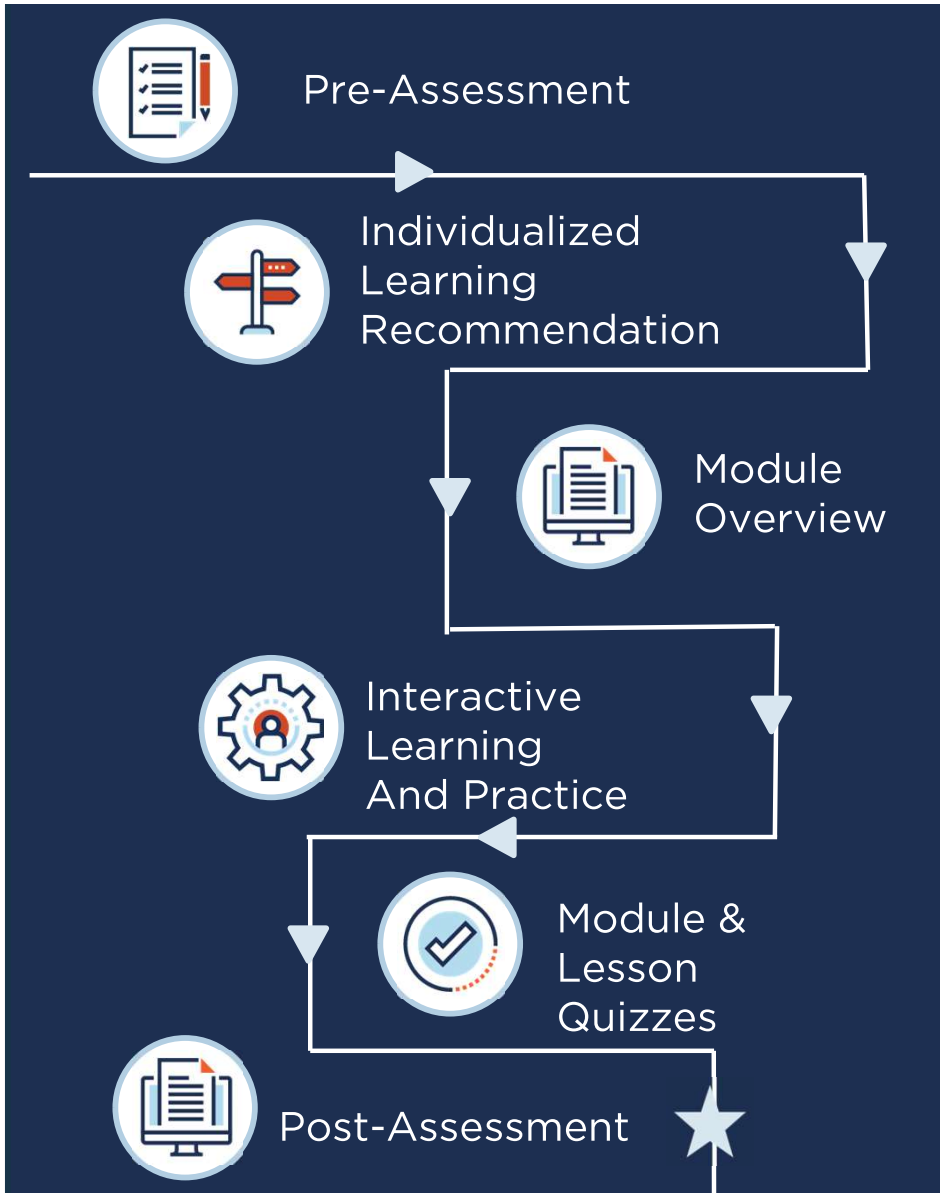
- Extensive didactic content delivered over 20 modules and 140 lessons

Interactive Practice

- Assess knowledge and reinforce comprehension throughout the training process with quizzes at the end of each lesson and module

Post-Assessment

- Post-assessment assess employee competency at the end of their training and provide a certificate of completion to those that successfully pass. (max 3 attempts



BACK

Drive Outcomes

PREP + REPORTING

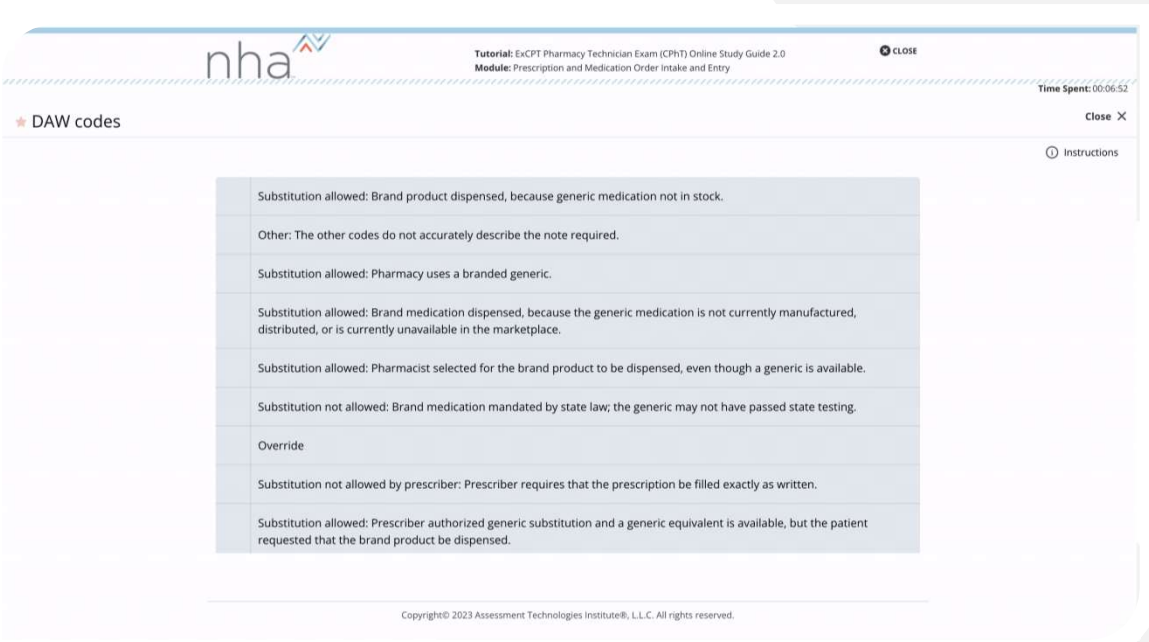
- ExCPT Practice Exam

ENGAGEMENT + LEARNING STYLES

- Preparing Prescriptions and Calculations in Study Guide

ALIGNMENT OF RESOURCES

- Pacing guides and timeline suggestions



Drive Outcomes to Industry Standards

BACK

PREP + REPORTING

- ExCPT Practice Exam

ENGAGEMENT + LEARNING STYLES

- Preparing Prescriptions and Calculations in Study Guide

ALIGNMENT OF RESOURCES

- Pacing guides and timeline suggestions

PharmaSeer + SG 24 week pacing guide

PharmaSeer™ | nha

Week 1	Resource Name	Activity	Time (mins)	Notes
	ExCPT Practice Exam #1 (Version A)	Complete practice exam and use Focused Review™ report to identify learning topic prioritization	130	
	PharmaSeer™	Module 1 - Introduction & Basic Overview	225	*Mark the first 10 flashcards by clicking the " " in the upper right hand corner of the card
	Flashcards/My Practice Activities	Module 1 & Top 200 medications flashcards, first 10*	60	
	Other Activities	Follow recommended activities in the Facilitator Tool Kit (FTK)	270	
		Total Time (mins)	685	11 hr 25 min
Week 2	**Resource Name**	**Activity**	**Time (mins)**	**Notes**
	PharmaSeer™	Module 2 - Prescription Medications: General	360	
	Flashcards/My Practice Activities	Module 2 & Top 200 medications flashcards, 11 - 20	60	
	Other Activities	Follow recommended activities in the Facilitator Tool Kit (FTK)	210	
		Total Time (mins)	630	10 hr 30 min
Week 3	**Resource Name**	**Activity**	**Time (mins)**	**Notes**
	PharmaSeer™	Module 3 - Prescription Medications: Controlled Substances	225	
	My Practice Activities	Module 3 & Top 200 medications flashcards, 21 - 30	60	
	Other Activities	Follow recommended activities in the Facilitator Tool Kit (FTK)	210	
		Total Time (mins)	495	8 hr 15 min
Week 4	**Resource Name**	**Activity**	**Time (mins)**	**Notes**
	PharmaSeer™	Module 4 - The Dispensing Process	450	
	Flashcards/My Practice Activities	Module 4 & Top 200 medications flashcards, 31 - 40	60	
	Other Activities	Follow recommended activities in the Facilitator Tool Kit (FTK)	330	
		Total Time (mins)	840	14 hr 0 min
Week 5	**Resource Name**	**Activity**	**Time (mins)**	**Notes**
	PharmaSeer™	Module 5 - Pharmacy Calculations	315	
	Flashcards/My Practice Activities	Module 5 & Top 200 medications flashcards, 41 - 50	60	
	Other Activities	Follow recommended activities in the Facilitator Tool Kit (FTK)	130	
		Total Time (mins)	505	8 hr 25 min

BACK

Develop Skills + Knowledge

ESSENTIAL SKILLS

- Mr. Ferguson in PersonAbility™ with baseline assessment

CORE KNOWLEDGE

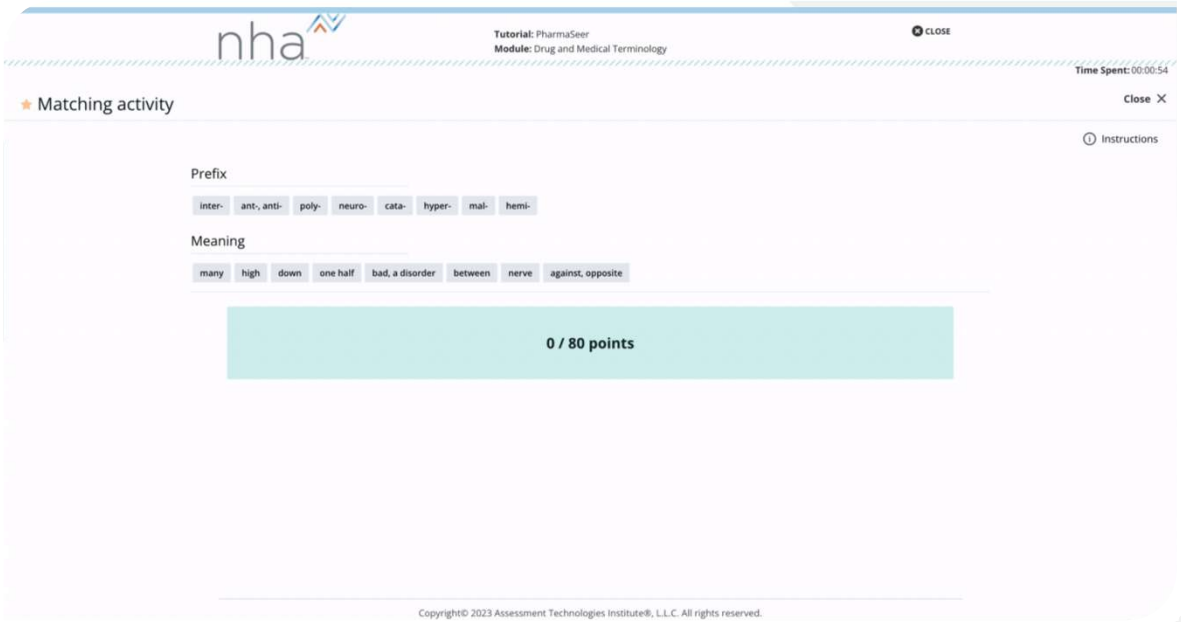
- Drug and Medical Terminology, PharmaSeer™
- Skills Competency Checklists

KNOWLEDGE CHECKS

- My Practice: Activities
- Quizzes

MATH SKILLS

- Module 5 in PharmaSeer™
- PharmaSeer Math™



BACK

Develop Skills + Knowledge

ESSENTIAL SKILLS

- Mr. Ferguson in PersonAbility™ with baseline assessment

CORE KNOWLEDGE

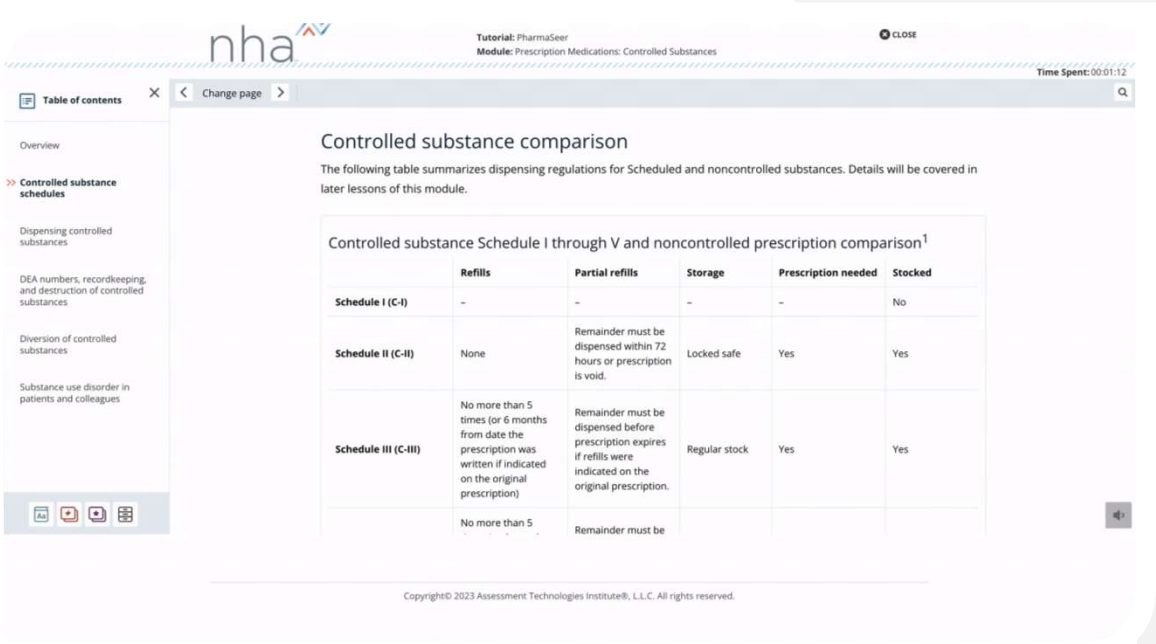
- Drug and Medical Terminology, PharmaSeer™
- Skills Competency Checklists

KNOWLEDGE CHECKS

- My Practice: Activities
- Quizzes

MATH SKILLS

- Module 5 in PharmaSeer™
- PharmaSeer Math™



BACK

Address Skills & Knowledge Gaps

ESSENTIAL SKILLS

- Mr. Ferguson in PersonAbility™ with baseline assessment

CORE KNOWLEDGE

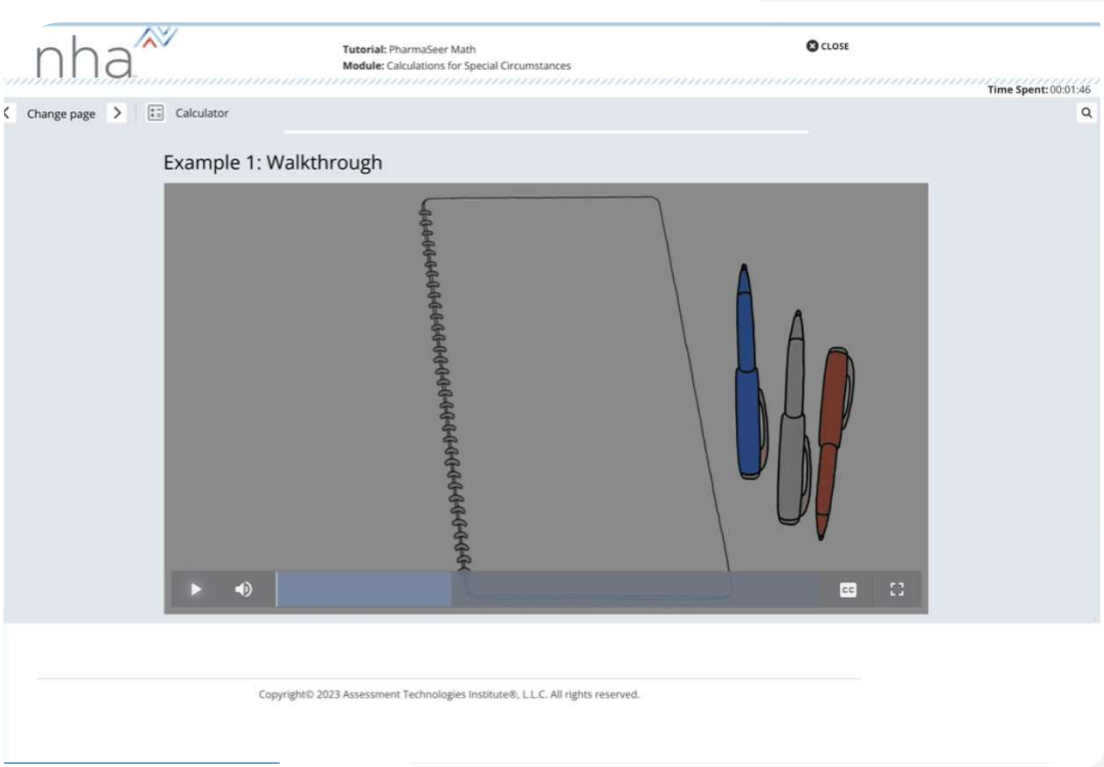
- Drug and Medical Terminology, PharmaSeer™
- Skills Competency Checklists

KNOWLEDGE CHECKS

- My Practice: Activities
- Quizzes

MATH SKILLS

- Module 5 in PharmaSeer™
- PharmaSeer Math™



BACK

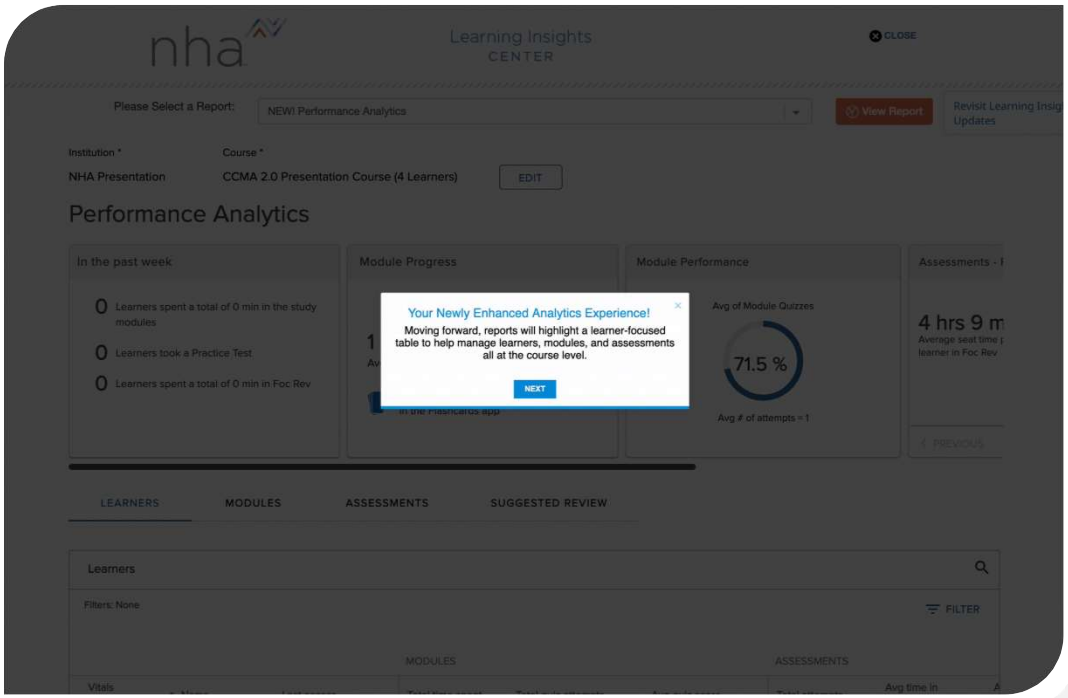
Simplify Implementation

EASE OF USE

- Single Platform with Centralized Reporting
- FTKs & Competency Checklist

RESOURCES FOR PLANNING & IMPLEMENTATION

- NHA Support & Customer Experience team
- Lessons Plans & Implementation Guide
- Live Remote Proctor available



BACK

Increase Retention & Recruiting

SKILLS VALIDATION

- Skill assessments, Pre-Assessment, Post Assessment

SCALABLE, FLEXIBLE & TRACKING

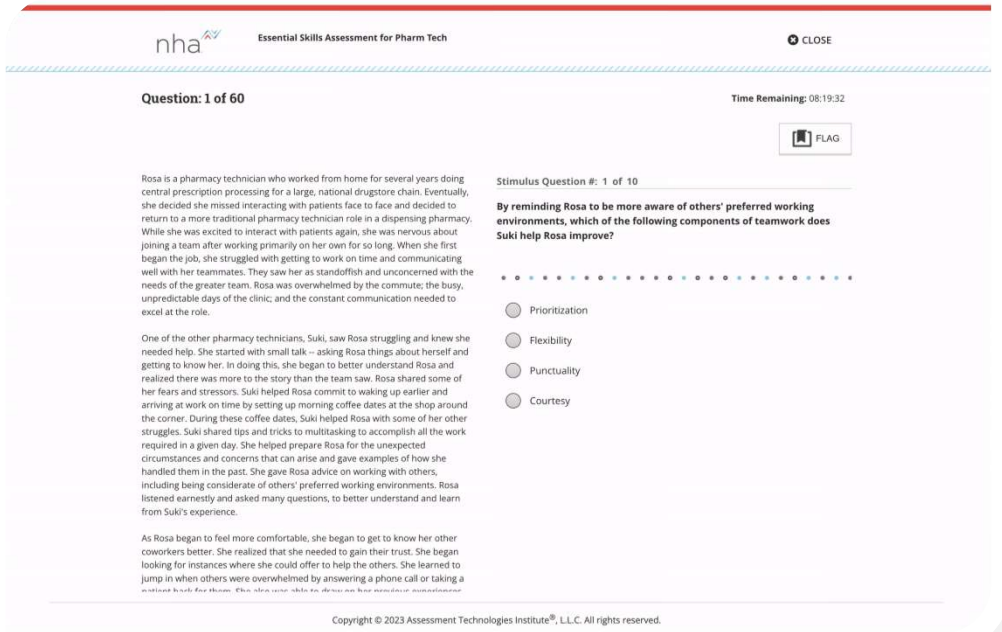
- Performance Analytics powered by Vitals™

LEARNING STYLES

- practice activities, interactive end of module quizzes

CONTINUING EDUCATION AND CERTIFICATION VERIFICATION

- PersonAbility™ is accredited for 9 hours of continuing education via ACPE



BACK

From Program to Practice

SKILLS VALIDATION

- Skill assessments, Pre-Assessment, Post Assessment

SCALABLE, FLEXIBLE & TRACKING

- Performance Analytics powered by Vitals™

LEARNING STYLES

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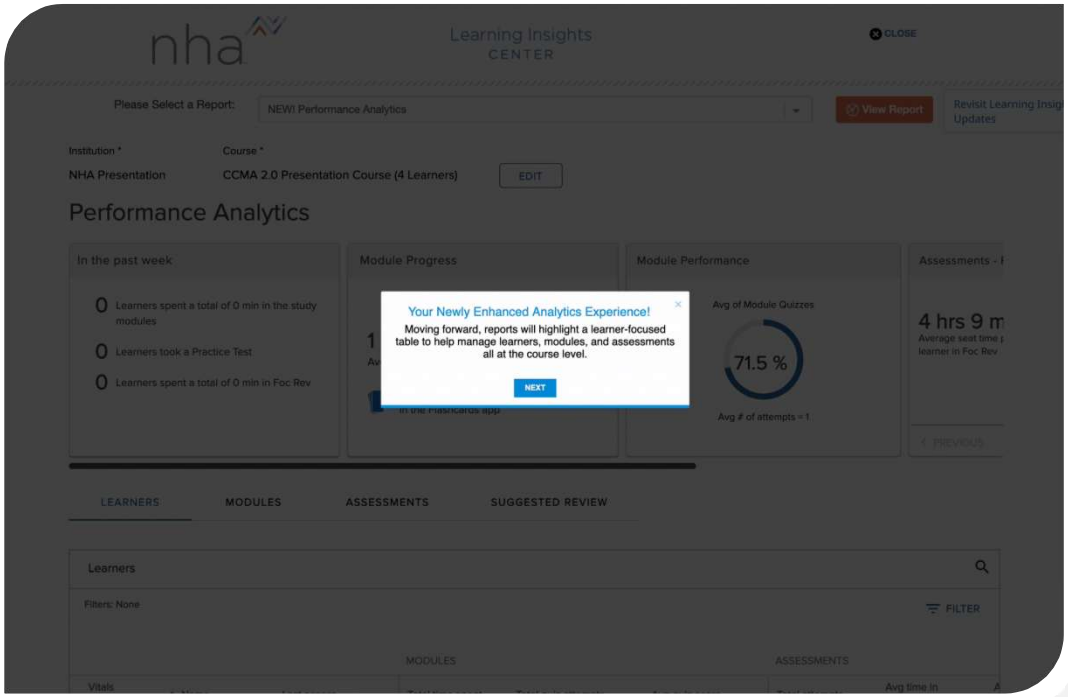

BACK

From Program to Practice

SKILLS VALIDATION

- Skill assessments, Pre-Assessment, Post Assessment

SCALABLE, FLEXIBLE & TRACKING

- Performance Analytics powered by Vitals™

LEARNING STYLES

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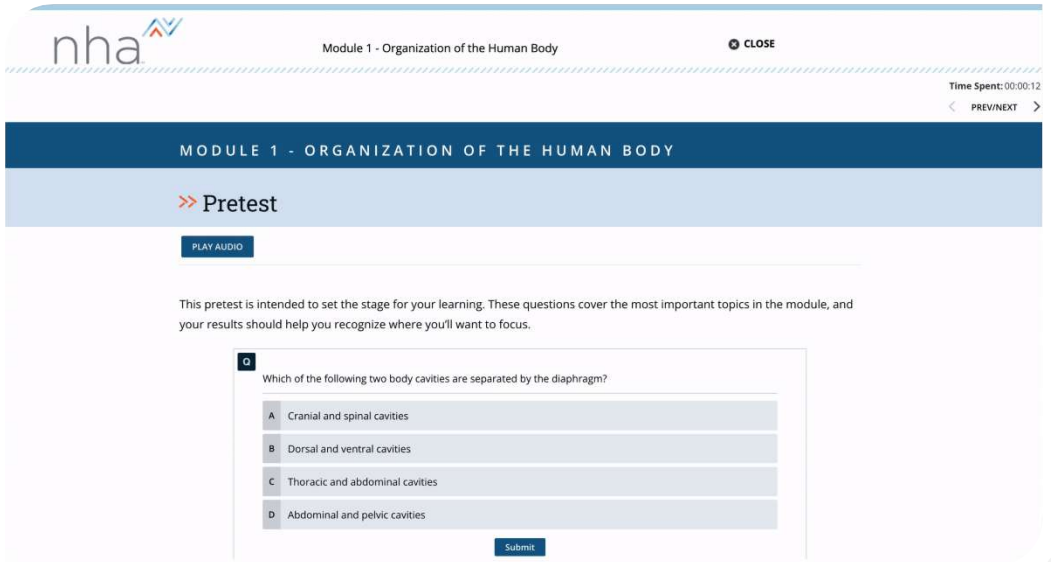
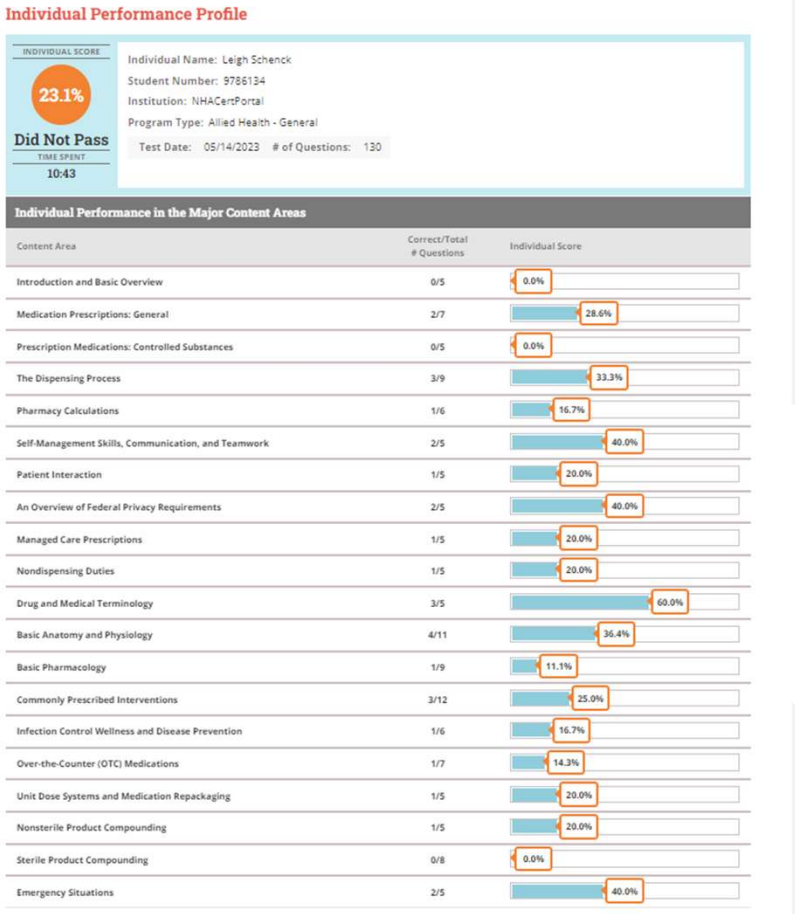


Pre + Post Assessments

BACK

Pre and Post Assessment

- Skill assessments, Pre-Assessment, Post Assessment



Individual Performance Profile

INDIVIDUAL SCORE
23.1%
Did Not Pass
TIME SPENT
10:43

Individual Name: Leigh Schenck
Student Number: 9786134
Institution: NHACertPortal
Program Type: Allied Health - General
Test Date: 05/14/2023 # of Questions: 130

Individual Performance in the Major Content Areas

Content Area	Correct/Total # Questions	Individual Score
Introduction and Basic Overview	0/5	0.0%
Medication Prescriptions: General	2/7	28.6%
Prescription Medications: Controlled Substances	0/5	0.0%
The Dispensing Process	3/9	33.3%
Pharmacy Calculations	1/6	16.7%
Self-Management Skills, Communication, and Teamwork	2/5	40.0%
Patient Interaction	1/5	20.0%
An Overview of Federal Privacy Requirements	2/5	40.0%
Managed Care Prescriptions	1/5	20.0%
Nondispensing Duties	1/5	20.0%
Drug and Medical Terminology	3/5	60.0%
Basic Anatomy and Physiology	4/11	36.4%
Basic Pharmacology	1/9	11.1%
Commonly Prescribed Interventions	3/12	25.0%
Infection Control Wellness and Disease Prevention	1/6	16.7%
Over-the-Counter (OTC) Medications	1/7	14.3%
Unit Dose Systems and Medication Repackaging	1/5	20.0%
Nonsterile Product Compounding	1/5	20.0%
Sterile Product Compounding	0/8	0.0%
Emergency Situations	2/5	40.0%

National Healthcareer Association

Services

Partner Support

Helping teams implement, engage, and deliver results

Onboarding & Setup

- Dedicated Success Team member to ensure guided onboarding for a smooth launch

Product Enablement

- Proven implementation strategies to drive learner success

Performance Insights

- Visibility into learner progress and outcomes
- Tools to identify at-risk students and support intervention

Certification & Testing Support

- Support for scheduling, results, and readiness

Ongoing Partnership

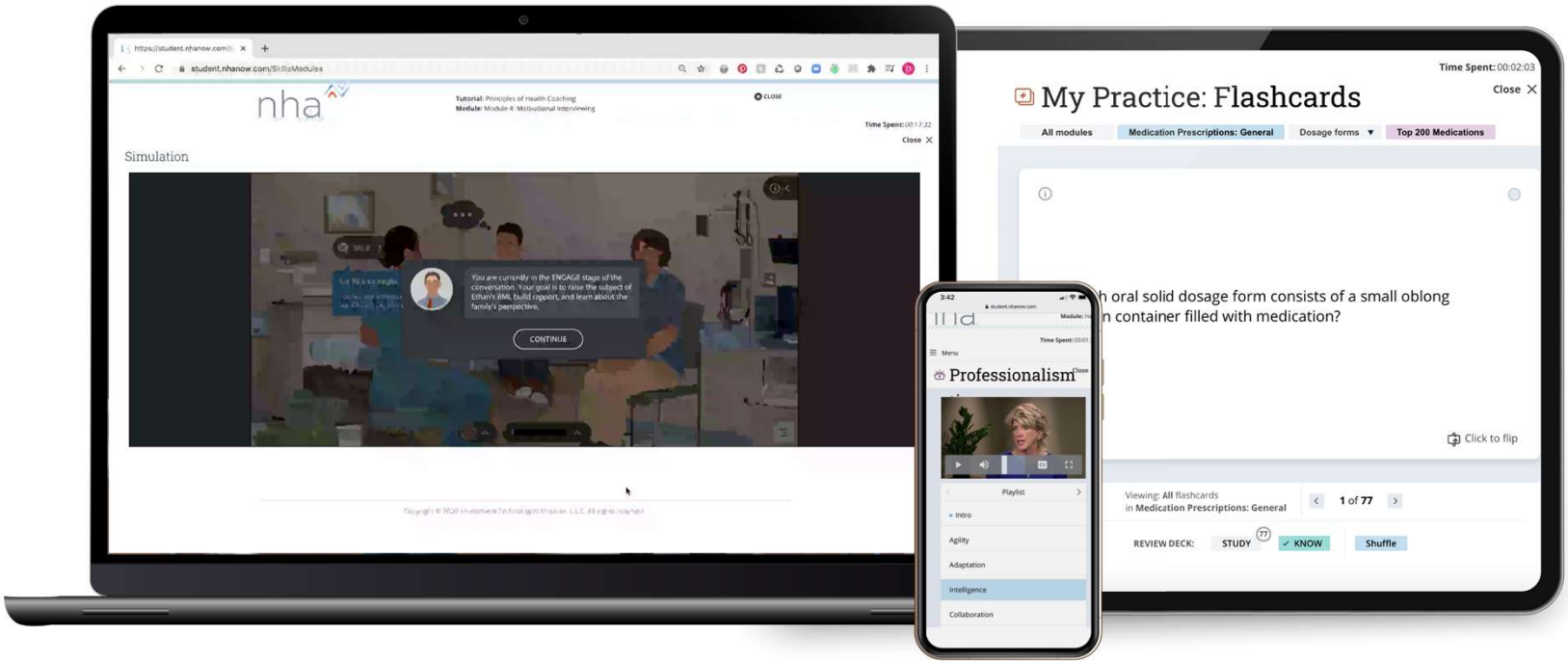
- Dedicated Client Experience Partner for continued success

> I'm blown away by how responsive NHA is. Also, all the trainings, webinars, and videos are so helpful.

> Communicating with our NHA rep is always easy. If I need to ask questions about the exam or planning for the exam, she would always help.

> Customer service is amazing in that questions are answered quickly and my representative remains consistent.

Visibility to Learner Engagement and Outcomes



Secure live remote proctoring | Safe, self-paced practice | Applied learning assessments
Study guide and practice tests | Interactive gaming, flashcards and simulation

nha

TOGETHER

We can empower people
to access a better future.

Prepared by:

Stacy Abernethy

PARTNERSHIP MANAGER

P: 913-721-5603
E: Stacy.Abernethy@nhanow.com

NHA is building the next generation of allied health professionals. Since 1989, we have helped over 1.25 million people access a better future in healthcare. From innovative learning solutions to certification and career development, we partner with individuals, educators and employers to elevate the learning experience, ensure practice and career readiness and drive positive outcomes for the industry, allied health professionals, and ultimately patients.

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ICE and NCCA

Let's clarify the relationship between I.C.E and the NCCA:

I.C.E. is a professional membership association that provides education, networking, and other resources for organizations and individuals who work in and serve the credentialing industry. I.C.E. is a leading developer of standards for both certification and certificate programs and it is both a provider of and a clearing house for information on trends in certification, test development and delivery, assessment-based certificate programs, and other information relevant to the credentialing community. I.C.E. is accredited by the American National Standards Institute as a standards developer.

NCCA is the accreditation that a program or exam may obtain to show standards of excellence in the industry. It was created in 1987 by I.C.E. to help ensure the health, welfare, and safety of the public through the accreditation of certification organizations that assess professional competence. Certification programs that receive NCCA Accreditation demonstrate compliance with the NCCA's Standards for the Accreditation of Certification Programs, which were the first standards for professional certification programs developed by the industry.

The Value of Being Accredited

Accreditation provides third party oversight of a conformity assessment system. It generates a mechanism for organizations to demonstrate to the profession it represents and the general public it serves that its credentialing program has been reviewed by a panel of impartial experts that have determined that their program has met the stringent standards set by the credentialing community. Accreditation provides organizations with a way to answer the question, "who reviewed your certificate or certification program?", a question often posed by members of an occupation, employers, and sometimes, the courts.

Accreditation applies to schools and programs as well, though that's not the type of accreditation NHA uses. For more information on scholastic accreditation, follow this link: Regional, National, and Specialized Accreditation

*https://www.nctrc.org/about-ncrtc/accreditation/

NHA's Partners at Ascend Learning

ati
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NASM
Nursing CE
PUBLIC SAFETY GROUP
ClubConnect
APEA Advanced Practice Education Associates
JONES & BARTLETT LEARNING
AFAA
BOARD VITALS
ExamFX
CDX
medhub
staffgarden
CLICKSAFETY
laudio
Clover Learning

R156. Commerce, Professional Licensing.
R156-17b. Pharmacy Practice Act Rule.
R156-17b-101. Title - Authority – [~~Organization and~~]Relationship to Rule R156-1.

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

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

(3) The organization of this rule and its relationship to Rule R156-1 is as described in Section R156-1-10[~~7~~]1.

R156-17b-102. Definitions.

Terms used in this rule are defined in Title 58, Chapter 1, Division of Professional Licensing Act, and Title 58, Chapter 17b, Pharmacy Practice Act. In addition:

(1) "Accredited by" means that, on the day the applicant for licensure completed the program, the program was:

(a) accredited; or

(b) in candidate status.

(2) "ACPE" means the American Council on Pharmaceutical Education or Accreditation Council for Pharmacy Education.

(3) "Analytical laboratory":

(a) means a facility in possession of prescription drugs for analysis; and

(b) does not include a laboratory possessing prescription drugs used as standards and controls in performing drug monitoring or drug screening analysis, if the prescription drugs are pre-diluted in a human or animal body fluid, human or animal body fluid components, organic solvents, or inorganic buffers at a concentration not exceeding one milligram per milliliter when labeled or otherwise designated as being for in-vitro diagnostic use.

(4) "Area of need" as used in Subsection 58-17b-612(1)(b)(i) means:

(a) a remote-rural hospital, as defined in Section 26B-2-213;

(b) a county of the fourth, fifth, or sixth class, as classified in Section [~~17-50-501~~]17-60-104; or

(c) any area where a demonstration of need is approved by the Division in collaboration with the Board, based on any factors affecting the access of persons in that area to pharmacy resources.

(5) "ASHP" means the American Society of Health System Pharmacists.

(6) "Authorized distributor of record" means a pharmaceutical wholesaler with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drugs. An ongoing relationship is deemed to exist if:

(a) the manufacturer and pharmaceutical wholesaler are part of an affiliated group, as defined by Section 1504 of the Internal Revenue Code; or

(b) the pharmaceutical wholesaler has a written agreement currently in effect with the manufacturer evidencing the ongoing relationship and is listed on the manufacturer's current list of authorized distributors of record.

(7) "Authorized personnel" means any person who is a part of the pharmacy staff who participates in the pharmacy's operational processes and contributes to the natural flow of pharmaceutical care.

(8) "Chain pharmacy warehouse" means a physical location for prescription drugs that acts as a central warehouse and performs intracompany sales or transfers of the prescription drugs to a group of chain pharmacies with the same common ownership and control.

(9) "Clinic" as used in Subsection 58-17b-625(3)(b) means a Class B pharmacy as defined in Subsection 58-17b-102(11), or a facility that provides outpatient health care services whose primary practice includes the therapeutic use of drugs related to a specific patient for:

(a) curing or preventing the patient's disease;

(b) eliminating or reducing the patient's disease; or

(c) arresting or slowing a disease process.

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

(11) "Co-licensed product" means a device or prescription drug for which two or more persons have the right to engage in the manufacturing, marketing, or both consistent with 21 CFR 203 (2021).

(12) "Community pharmacy" as used in Subsection 58-17b-625(3)(b) means a Class A pharmacy as defined in Subsection 58-17b-102(10).

(13) "Compounding," as defined in Subsection 58-17b-102(18), in accordance with 21 U.S.C. 353a(e) Pharmacy Compounding, does not include:

(a) mixing, reconstituting, or other such acts that are performed in accordance with directions in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling; or

(b) the addition of flavoring agents to conventionally manufactured and commercially prepared available liquid medications, if the flavoring agents:

(i) are therapeutically inert; and

(ii) do not exceed 5% of a preparation's total volume.

(14) "Consulting pharmacist" means a licensed pharmacist who provides consultation on an aspect of a pharmaceutical administration facility under Section R156-17b-614c.

(15) "Counterfeit prescription drug" has the meaning given to the term "counterfeit drug" in 21 USC 321(g)(2) as applied to prescription drugs.

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

(17) "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.

(18) "Designated representative" or "DR" means an individual supervising the licensed facility in accordance with Subsections R156-17b-615([4]6) and ([~~5~~]7).

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

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

(21) "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 Title 58 chapters:

(A) Chapter 67, Utah Medical Practice Act;

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

(C) Chapter 70a, Utah 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(14);
(b) meets requirements in Subsection 58-17b-803(4)(c); and
(c) can document successful completion of a formal or on-the-job dispensing training program under Section R156-17b-622.

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

(23) "DSCSA" means Title II of the Drug Quality and Security Act of 2013, the Drug Supply Chain Security Act, 113 Pub. L. No. 54, 127 Stat. 587 (2013), and any regulations promulgated pursuant to the DSCSA.

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

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

(26) "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.

(27) "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.

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

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

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

(31) "FDA-Approved" means that the federal Food, Drug, and Cosmetic Act, 21 USC 301 et seq. and regulations promulgated thereunder permit the subject drug or device to be lawfully manufactured, marketed, distributed, and sold.

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

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

(34) "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.

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

(a) "Caution: federal law prohibits dispensing without prescription";

(b) "Caution: federal law restricts this drug to use by or on the order of a licensed veterinarian"; or

(c) "Rx only".

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

(37) "Managerial control" means the ability, regardless of title, to directly manage the finances, strategic initiatives, and personnel of a pharmacy or pharmaceutical facility, including:

(a) taking on debt obligations;

(b) distributing profits;

(c) determining fees and costs charged for products or services offered by the pharmacy or pharmaceutical facility;

(d) hiring, firing, or promoting any personnel, including the PIC; or

(e) changing the location or name of the pharmacy or pharmaceutical facility.

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

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

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

(b) disposable or semi-disposable and non-reusable.

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

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

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

(43) "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.

(44) "Normal distribution channel" means a chain of custody for a prescription drug sent:

(a) (i) directly from the manufacturer;

(ii) by drop-shipment;

(iii) via intracompany transfer from the manufacturer; or

(iv) from the manufacturer's:

(A) co-licensed partner;

(B) third party logistics provider; or

(C) exclusive distributor;

(b) to:

(i) a pharmacy or other designated persons authorized to dispense or administer prescription drugs to a patient;

(ii) a chain pharmacy warehouse that performs intracompany sales or transfers of such drugs to a group of pharmacies under common ownership and control;

(iii) a cooperative pharmacy warehouse to a pharmacy that is a member of the pharmacy buying cooperative or GPO to a patient;
(iv) an authorized distributor of record, and then to either a pharmacy or other designated persons authorized to dispense or administer such drug for use by a patient;
(v) 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
(vi) an authorized distributor of record to another authorized distributor of record to a licensed pharmaceutical facility or a licensed healthcare practitioner authorized to dispense or administer such drug for use by a patient.

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

(46) "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 (46)(a), one of the following facilities:

(i) an office of a licensed prescribing practitioner in Utah;

(ii) a long-term care facility where the patient resides; or

(iii) a hospital, office, clinic, or another medical facility that provides health care services.

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

(48) "Pharmacy facility" means the same as "Pharmaceutical facility" defined in Subsection 58-17b-102(46).

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

(50) "Prepackaged" or "Prepackaging" means transferring a drug, manually or by use of an automated pharmacy system, from a manufacturer's or distributor's original container to another container before 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.

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

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

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

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

(55) "Qualifying Ownership Change" means any transaction or series of transactions that results in a change in the ownership and managerial control of a pharmaceutical facility, but does not include changes in ownership:

(a) caused by changes in stockholders in publicly listed corporations whose stock is publicly traded;
(b) that do not result in a change in managerial control, including changes in the type of corporate entity under which the pharmaceutical facility is held;
(c) constituting less than 50% of the total ownership of the pharmaceutical facility; or
(d) of a parent entity holding an equitable interest in a pharmaceutical facility as a subsidiary, if the equitable interest constitutes less than 50% of the total ownership interest of the pharmaceutical facility.

(56) "Refill" means to fill again.

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

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

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

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

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

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

(63) "Self-administered hormonal contraceptive" means the same as defined in Subsection 26B-4-501(2[~~2~~]4).

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

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

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

(67) "Telepharmacy system" means any telecommunication or information technology system, or combination of systems, that monitors the preparation and dispensing of prescription drugs and provides for related drug review and HIPAA-compliant patient counseling services.

(68) "Therapeutically Similar Drug List" under Subsection R156-17b-612c(1) means the list approved by the Division in collaboration with the Board, which can be found on the Division's website at https://commerce.utah.gov/dopl/pharmacy/resources/.

(6[~~8~~]9) "Third party logistics provider" means anyone who contracts with a prescription drug manufacturer to provide or coordinate warehousing, distribution, or other similar services on behalf of a manufacturer, but does not take title to the prescription drug or have any authoritative control over the prescription drug's sale.

([~~69~~]70) "Unauthorized personnel" means a person not participating in the operational processes of the pharmacy who in some way would interrupt the natural flow of pharmaceutical care.

(7[~~0~~]1) "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.

(72) "Unlawful conduct" as defined in Subsections 58-1-102 and 58-17b-501(3)(b) and under Rule R156-17b does not include using the word "pharmacy," "drugstore," or any other word or combination of words of the same or similar meaning, or any sign or graphic representation that would indicate a pharmacy is at an address or location, if:

(a) the address or location is:

(i) eligible for or listed on the National Register of Historic Places;

(ii) recognized by the Utah State Historic Preservation Office; or

(iii) otherwise recognized by a historic society or other organization dedicated to promoting the history of a particular place, group of people, or topic;

(b) the use is only for historic purposes, and does not include conducting or transacting pharmacy business or providing pharmacy services; and

(c) the Division has been notified in writing of the use at that address or location.

(7[~~1~~]3) "Unprofessional conduct," as defined in Title 58, Chapter 1, Division of Professional Licensing Act, Title 58, Chapter 17b, Pharmacy Practice Act, and Subsection 58-1-203(1)(e) is further defined in Section R156-1-501 and Section R156-17b-502.

(74) "USP" means the United States Pharmacopeia-National Formulary (USP 41-NF 36), including the First Supplement, dated November 1, 2023. The following general chapters are incorporated by reference:.

(a) USP <795> on Pharmaceutical Compounding -- Nonsterile Preparations;

(b) USP <797> on Pharmaceutical Compounding -- Sterile Preparations;

(c) USP <800> on Hazardous Drugs---Handling in Healthcare Settings; and

(d) USP <825> on Radiopharmaceuticals -- Preparation, Compounding, Dispensing, and Repackaging.

(75) "Utah Guidance for Diabetic Therapeutic Equivalents" under Subsections 58-17b-608.1(7) and R156-17b-612b(2) means the guidance approved by the Division in collaboration with the Board, which can be be found on the Division's website at https://commerce.utah.gov/dopl/pharmacy/resources/.

(76) "Utah Guidance for Dispensing by Health Department Nurse of STI Drug" under Section R156-17b-628 means the guidance approved by the Division in collaboration with the Board, which can be found on the Division's website at https://commerce.utah.gov/dopl/pharmacy/resources/.

(77) "Utah Guidance for Epinephrine" under Subsections 58-17b-627(3)(a)(viii) and R156-17b-627(2)(g) means the guidance approved by the Division in collaboration with the Board, which can be found on the Division's website at https://commerce.utah.gov/dopl/pharmacy/resources/.

(78) "Utah Guidance for Fluoride" under Subsections 58-17b-627(3)(a)(vi) and R156-17b-627(2)(e) means the guidance approved by the Division in collaboration with the Board, which can be found on the Division's website at https://commerce.utah.gov/dopl/pharmacy/resources/.

(79) "Utah Guidance for Naloxone" under Subsections 58-17b-627(3)(a)(v) and R156-17b-627(2)(d) means the guidance approved by the Division in collaboration with the Board, which can be found on the Division's website at https://commerce.utah.gov/dopl/pharmacy/resources/.

(80) "Utah Guidance for PrEP and PEP" under Subsections 58-17b-627(3)(a)(i) and (ii) and R156-17b-627(2)(a) means the guidance approved by the Division in collaboration with the Board, which can be found on the Division's website at https://commerce.utah.gov/dopl/pharmacy/resources/.

([~~72~~]81) "Utah Guidance for Self-Administered Hormonal Contraceptives" under Subsection R156-17b-621b(2)(c) means the guidance approved [~~September 28, 2021~~]by the Division in collaboration with the Board [~~of Pharmacy~~]and Medical Licensing Board, which can be found on the Division's website at https://[~~dopl~~]commerce.utah.gov/dopl/pharmacy/resources[~~, and is incorporated by reference~~].

(82) "Utah Guidance for Tobacco Cessation Products" under Subsections 58-17b-627(3)(a)(iv) and R156-17b-627(2)(c) means the guidance approved by the Division in collaboration with the Board, which can be found on the Division's website at https://commerce.utah.gov/dopl/pharmacy/resources/.

(83) "Utah Guidance for Vaccine Prescription and Administration" under Subsections 58-17b-627(3)(a)(vii) and R156-17b-627(2)(f) means the guidance approved by the Division in collaboration with the Board and the Medical Licensing Board, which can be found on the Division website at https://commerce.utah.gov/dopl/pharmacy/resources/.

([~~73~~]84) "Utah Hormonal Contraceptive Self-Screening Risk Assessment Questionnaire" under Subsection R156-17b-610(8)(a) means the guidance approved [~~September 28, 2021~~]by the Division in collaboration with the Board [~~of Pharmacy~~]and Medical Licensing Board, which can be found on the Division's website at https://[~~dopl~~]commerce.utah.gov/dopl/pharmacy/resources/[~~, and is incorporated by reference~~].

[~~(74) "USP" means the United States Pharmacopeia National Formulary (USP 41 NF 36), including the First Supplement, dated November 1, 2023. The following general chapters are incorporated by reference:.~~

~~(a) USP <795> on Pharmaceutical Compounding -- Nonsterile Preparations;~~

~~(b) USP <797> on Pharmaceutical Compounding -- Sterile Preparations;~~

~~(c) USP <800> on Hazardous Drugs -- Handling in Healthcare Settings; and~~

~~(d) USP <825> on Radiopharmaceuticals -- Preparation, Compounding, Dispensing, and Repackaging.~~

~~(75) "Vaccine Administration Protocol" means the Vaccine Administration Protocol: Standing Order to Administer Immunizations and Emergency Medications, adopted September 1, 2023, by the Division in collaboration with the Board and Medical Licensing Board, which is incorporated by reference.~~]

([~~76~~]85) "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.

([~~77~~]86) "Wholesale distribution" means the same as 21 CFR 203.3(cc) (2021).

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

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

(2) A graduate of a U.S. pharmacy school shall have at least 1,740 hours of practice obtained according to the Accreditation Council for Pharmacy Education (ACPE), Accreditation Standards and Key Elements for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree, effective June 2025[~~July 1, 2016 ("Standards 2016")~~], which is incorporated by reference.

(3) (a) A graduate of a foreign pharmacy school and who has obtained a certification of equivalency under Subsection 58-17b-303(2) shall have at least 1,440 hours of supervised pharmacy practice in the United States.

(b) The Division in collaboration with the Board may credit up to 500 hours toward the requirement of Subsection R156-17b-303b(3)(a) for a graduate's other experience substantially related to the practice of pharmacy.

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

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

R156-17b-30[~~7~~]6. Qualifications for Licensure - Criminal Background Checks.

(1) Under Section 58-17b-306, [~~A~~]an applicant for licensure as a pharmacy shall document, to the satisfaction of the Division, the owners and management of the pharmacy and the facility in which the pharmacy is located.

(2) The following individuals associated with an applicant for licensure as a pharmacy shall be subject to the criminal background check requirements set forth in Section 58-17b-30[~~7~~]6:

(a) the PIC;

(b) the PIC's immediate supervisor;

(c) the senior person in charge of the facility in which the pharmacy is located;

(d) others associated with management of the pharmacy or the facility in which the pharmacy is located as determined necessary by the Division [~~in order~~]to protect public health, safety, and welfare; and

(e) owners of the pharmacy or the facility in which the pharmacy is located as determined necessary by the Division [~~in order~~]to protect public health, safety, and welfare.

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

This section establishes procedures required in Sections 58-1-308, 58-17b-308, and 58-17b-506.

(1) The renewal date for the two-year renewal cycle applicable to licensees under Title 58, Chapter 17b is established in Section R156-1-308a.

(2) Renewal and reinstatement procedures shall be in accordance with Sections R156-1-308a through R156-1-308l, except as provided in Subsections (3) and (4).

(3) A pharmacist whose license was active and in good standing before its expiration may apply for reinstatement, under the following practice re-entry requirements:

(a) if the application for re-entry is between two years and five years after the date of expiration, an applicant for reinstatement shall submit documentation of compliance with current continuing education as required in Subsection R156-17b-309(1); or

(b) if the application for re-entry is more than five years after the date of license expiration, an applicant for reinstatement shall retake the examinations required for licensure under Subsection R156-17b-303c.

(4) A pharmacy technician whose license was active and in good standing before its expiration may apply for reinstatement in accordance with the following practice re-entry requirements:

(a) if the application for re-entry is between two years and five years after the date of expiration, an applicant for reinstatement shall submit documentation of current continuing education as required in Subsection R156-17b-309(2); or

(b) if the application for re-entry is more than five years after the date of expiration, an applicant for reinstatement shall retake the examinations required for licensure under Section R156-17b-303c.

(5) The Division, in collaboration with the Board, may approve the extension of an intern license upon the request of the licensee, if the intern lacks the required number of internship hours for licensure.

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

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

(a) in accordance with state and federal laws and rules; and

(b) under the general supervision of the pharmacist as defined in Subsection R156-1-102a([4]1)(c).

(2) A pharmacist retains accountability for the appropriate delegation of dispensing [~~s~~]tasks.

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

(4) A covered provider may not:

(a) further delegate to another person any dispensing task delegated to the covered provider by the pharmacist; or

(b) expand the scope of a delegated dispensing task without the express permission of the pharmacist.

R156-17b-402. Administrative Penalties.

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

TABLE 1[~~402~~

~~FINE SCHEDULE~~]			
[~~SUBSECTION~~	Violation[~~IOLATION~~]	First[~~IRST~~] Offense[~~FFENSE~~] Penalty	Subsequent[~~UBSEQUENT~~] Offense[~~FFENSE~~] Penalty
~~(1)~~	58-1-501(1)(a)	$[-]500 - $[-]2,000	$[-]2,000 - $[-]10,000
~~(2)~~	58-1-501(1)(b)	$[-]500 - $[-]2,000	$[-]2,000 - $[-]10,000
~~(3)~~	58-1-501(1)(c)	$[-]500 - $[-]1,000	$[-]1,000 - $[-]5,000
~~(4)~~	58-1-501(1)(d)	$[-]500 - $[-]1,000	$[-]1,000 - $[-]5,000
~~(5)~~	58-1-501(1)(e)	$[-]100 - $[-]2,000	$[-]2,000 - $[-]10,000
~~(6)~~	58-1-501(1)(f)(i)(A)	$[-]500 - $[-]2,000	$[-]2,000 - $[-]10,000
~~(7)~~	58-1-501(1)(f)(i)(B)	$[-]500 - $[-]2,000	$[-]2,000 - $[-]10,000
~~(8)~~	58-1-501(1)(g)	$[-]500 - $[-]2,000	$[-]2,000 - $[-]10,000
~~(9)~~	58-1-501(2)(a)(i)	$[-]100 - $[-]2,000	$[-]2,000 - $[-]10,000
~~(10)~~	58-1-501(2)(a)(ii)	$[-]500 - $[-]2,000	$[-]2,000 - $[-]10,000
~~(11)~~	58-1-501(2)(a)(iii)	$[-]500 - $[-]2,000	$[-]2,000 - $[-]10,000
~~(12)~~	58-1-501(2)(a)(iv)	$[-]100 - $[-]500	$[-]200 - $[-]1,000
~~(13)~~	58-1-501(2)(a)(v)	$[-]100 - $[-]500	$[-]200 - $[-]1,000
~~(14)~~	58-1-501(2)(a)(vi)	$[-]100 - $[-]500	$[-]200 - $[-]1,000
~~(15)~~	58-1-501(2)(a)(vii)	$[-]500 - $[-]2,000	$[-]2,000 - $[-]10,000
~~(16)~~	58-1-501(2)(a)(viii)	$[-]100 - $[-]500	$[-]200 - $[-]1,000
~~(17)~~	58-1-501(2)(a)(ix)	$[-]100 - $[-]500	$[-]200 - $[-]1,000
~~(18)~~	58-1-501(2)(a)(x)	$[-]100 - $[-]500	$[-]200 - $[-]1,000
	58-1-501(2)(a)(xi)		
~~(19)~~	58-1-501(2)(a)(xii)	$[-]100 - $[-]1,000	$[-]500 - $[-]2,000
~~(20)~~	58-1-501(2)(a)(xiii)	$[-]100 - $[-]500	$[-]200 - $[-]1,000
~~(21)~~	58-1-501(2)(a)(xiv[~~ii~~])(A)	$[-]500 - $[-]2,000	$[-]2,000 - $[-]10,000
~~(22)~~	58-1-501(2)(a)(xiv[~~ii~~])(B)	$500 - $[-]2,000	$[-]2,000 - $[-]10,000
~~(23)~~	58-1-501(2)(a)(x[~~i~~]v)	$[-]500 - $[-]2,000	$[-]2,000 - $[-]10,000
~~(24)~~	58-1-501(2)(a)(xvi)	$[-]500 - $[-]2,000	$[-]2,000 - $[-]10,000
~~(25)~~	58-1-501(2)(a)(xvii)	$[-]500 - $[-]2,000	$[-]2,000 - $[-]10,000
	58-1-501(2)(a)(xviii)	$100 - $500	$200 - $1,000
~~(26)~~	58-1-501.5	$[-]500 - $[-]2,000	$[-]2,000 - $[-]10,000
~~(27)~~	R156-1-501(1)	$[-]500 - $[-]2,000	$[-]2,500 - $[-]10,000
~~(28)~~	R156-1-501(2)	$[-]500 - $[-]2,000	$[-]2,500 - $[-]10,000
~~(29)~~	R156-1-501(3)	$[-]500 - $[-]2,000	$[-]2,500 - $[-]10,000
~~(30)~~	R156-1-501(4)	$[-]500 - $[-]2,000	$[-]2,500 - $[-]10,000
~~(31)~~	R156-1-501(5)	$[-]500 - $[-]2,000	$[-]2,500 - $[-]10,000
~~(32)~~	R156-1-501(6)	$[-]500 - $[-]2,000	$[-]2,500 - $[-]10,000
	R156-1-501(7)	$500 - $2,000	$2,000 - $10,000
~~(33)~~	58-17b-501(1)	$[-]500 - $[-]2,000	$[-]5,000
~~(34)~~	58-17b-501(2)	$[-]100 - $[-]1,000	$[-]500 - $[-]2,000
~~(35)~~	58-17b-501(3)(a)	$[-]500 - $[-]2,000	$[-]2,000 - $[-]10,000

~~(36)~~	58-17b-501(3)(b)	$[-]500 - $[-]2,000	$[-]2,000 - $[-]10,000
~~(37)~~	58-17b-501(4)	$[-]1,000 - $[ ]5,000	$[-]10,000
~~(38)~~	58-17b-501(5)	$[-]100 - $[-]500	$[-]200 - $[-]1,000
~~(39)~~	58-17b-501(6)	$[-]500 - $[-]2,000	$[-]2,000 - $[-]10,000
~~(40)~~	58-17b-501(7)	$[-]500 - $[-]2,000	$[-]2,000 - $[-]10,000
~~(41)~~	58-17b-501(8)	$[-]500 - $[-]2,000	$[-]2,500 - $[-]10,000
~~(42)~~	58-17b-501(9)	$[-]500 - $[-]1,000	$[-]1,500 - $[-]5,000
~~(43)~~	58-17b-501(10)	$[-]500 - $[-]2,000	$[-]2,500 - $[-]10,000
~~(44)~~	58-17b-501(11)	$[-]500 - $[-]2,000	$[-]2,500 - $[-]10,000
~~(45)~~	58-17b-501(12)	$[-]1,000 - $[-] 5,000	$[-]10,000
~~(46)~~	58-17b-501(13)	$[-]100 - $[-]500	$[-]1,000 - $[-]2,500
~~(47)~~	58-17b-502(1)(a)	$[-]500 - $[-]2,000	$[-]2,500 - $[-]10,000
~~(48)~~	58-17b-502(1)(b)	$[-]2,500 - $[ ]5,000	$[-]5,500 - $[-]10,000
~~(49)~~	58-17b-502(1)(c)	$[-]1,000 - $[ ]5,000	$[-]10,000
~~(50)~~	58-17b-502(1)(d)	$[-]500 - $[-]2,000	$[-]2,500 - $[-]10,000
~~(51)~~	58-17b-502(1)(e)	$[-]1,000 - $[ ]5,000	$[-]10,000
~~(52)~~	58-17b-502(1)(f)	$[-]500 - $[-]2,000	$[-]2,500 - $[-]10,000
~~(53)~~	58-17b-502(1)(g)	$[-]500 - $[-]2,000	$[-]2,500 - $[-]10,000
~~(54)~~	58-17b-502(1)(h)	$[-]100 - $[-]500	$[-]500 - $[-]1,000
~~(55)~~	58-17b-502(1)(i)	$[-]500 - $[-]2,000	$[-]2,000 - $[-]10,000
~~(56)~~	58-17b-502(1)(j)	$[-]100 - $[-]500	$[-]500 - $[-]1,000
~~(57)~~	58-17b-502(1)(k)	$[-]100 - $[-]500	$[-]2,000 - $[-]10,000
~~(58)~~	58-17b-502(1)(l)	$[-]100 - $[-]500	$[-]500 - $[-]1,000
~~(59)~~	58-17b-502(1)(m)	$[-]500 - $[-]1,000	$[-]2,500 - $[-]5,000
~~(60)~~	58-17b-502(1)(n)	$[-]100 - $[-]500	$[-]500 - $[-]1,000
~~(61)~~	58-17b-502(1)(o)	$[-]100 - $[-]500	$[-]500 - $[-]1,000
~~(62)~~	58-17b-502(1)(p)	$[-]2,500 - $[ ]5,000	$[-]5,000 - $[-]10,000
~~(63)~~	R156-17b-502(1)	$[-]250 - $[-]500	$[-]2,000 - $[-]10,000
~~(64)~~	R156-17b-502(2)(a)	$[-]250 - $[-]500	$[-]500 - $[-]750
~~(65)~~	R156-17b-502(2)(b)	$[-]500 - $[-]2,000	$[-]2,500 - $[-]10,000
~~(66)~~	R156-17b-502(3)	$[-]100 - $[-]500	$[-]500 - $[-]1,000
~~(67)~~	R156-17b-502(4)	$[-]50 - $100	$[-]200 - $[-]300
~~(68)~~	R156-17b-502(5)	$[-]100 - $[-]200	$[-]200 - $[-]500
~~(69)~~	R156-17b-502([~~6~~]5)	$[-]500 - $[-]1,000	$[-]2,000 - $[-]10,000
~~(70)~~	R156-17b-502([~~7~~]6)	$[-]500 - $[-]2,000	$[-]2,000 - $[-]10,000
~~(71)~~	R156-17b-502([~~8~~]7)	$[-]100 - $[-]250	$[-]300 - $[-]500
~~(72)~~	R156-17b-502([~~9~~]8)	$250 - $1,000	$[-]500 - $[-]5,000

~~(73)~~	R156-17b-502([~~10~~]9)(a)	$[-]50 - $[-]100	$[-]250 - $[-]500
~~(74)~~	R156-17b-502([~~10~~]9)(b)	$[-]250 - $[-]500	$[-]750 - $[-]1,000
~~(75)~~	R156-17b-502([~~11~~])10	$[-]500 - $[-]2,000	$[-]2,000 - $[-]10,000
~~(76)~~	R156-17b-502(1[~~2~~]1)(a)	$[-]100 - $[-]250	$[-]500 - $[-]2,500
~~(77)~~	R156-17b-502(1[~~2~~]1)(b)	$[-]250 - $[-]1,000	$[-]500 - $[-]5,000
~~(78)~~	R156-17b-502(1[~~3~~]2)(a)	$[-]50 - $[-]100	$[-]250 - $[-]500
~~(79)~~	R156-17b-502(1[~~3~~]2)(b)	$[-]250 - $[-]500	$[-]1,000 - $[-]2,000
~~(80)~~	R156-17b-502(1[~~4~~]3)(a)	$[-]500 - $[-]2,500	$[-]5,000 - $[-]10,000
~~(81)~~	R156-17b-502(1[~~4~~]3)(b)	$[-]2,000 per occurrence	
~~(82)~~	R156-17b-502(1[~~5~~]4)	[~~double original penalty, up to $ 10,000~~]	double original penalty, up to $10,000
~~(83)~~	R156-17b-502(1[~~6~~]5)	$[-]500 - $[-]2,000	$[-]2,000 - $[-]10,000
~~(84)~~	R156-17b-502(1[~~7~~]6)	$[-]1,000 - $[ ]5,000	$[-]10,000
~~(85)~~	R156-17b-502(1[~~8~~]7)	$[-]500 - $[-]2,500	$[-]5,000 - $[-]10,000
~~(86)~~	R156-17b-502(1[~~9~~]8)	$[-]100 - $[-]500	$[-]200 - $[-]1,000
~~(87)~~	R156-17b-502([~~20~~]19)	$[-]100 - $[-]500	$[-]200 - $[-]1,000
~~(88)~~	R156-17b-502(2[~~1~~]0)	$[-]100 - $[-]500	$[-]200 - $[-]1,000
~~(89)~~	R156-17b-502(2[~~2~~]1)	$[-]500 - $[-]2,000	$[-]2,000 - $[-]10,000
~~(90)~~	R156-17b-502(2[~~3~~]2)(a)	$[-]100 - $[-]300	$[-]500 - $[-]1,000
~~(91)~~	R156-17b-502(2[~~3~~]2)(b)	$[-]250 - $[-]500	$[-]500 - $[-]1,250
~~(92)~~	R156-17b-502(2[~~4~~]3)	$[-]100 - $[-]500	$[-]500 - $[-]1,000
~~(93)~~	R156-17b-502(2[~~5~~]4)	$[-]500 - $[-]2,000	$[-]2,500 - $[-]10,000
~~(94)~~	R156-17b-502(2[~~6~~]5)	$[-]500 - $[-]2,000	$[-]2,500 - $[-]10,000
~~(95)~~	58-37-[~~8~~]304([~~11~~])	$[-]1,000-$[ ]5,000	$[-]5,000[~~- $ 10,000~~]
	58-37-304(12)	$100 - $500	$500 - $1,000
	58-37-304(13)	$500 - $2,000	$2,500 - $5,000
	58-37-304(14)	$500 - $2,500	$5,000
	58-37-304(15)	$500 - $2,500	$5,000
~~(96)~~	R156-37-502(1)(a)	$[-]500 - $[-]2,000	$[-]2,500 - $[-]10,000
~~(97)~~	R156-37-502(1)(b)	$[-]500 - $[-]2,000	$[-]2,500 - $[-]10,000
~~(98)~~	R156-37-502(2)	$[-]500 - $[-]2,000	$[-]2,500 - $[-]10,000

~~(99)~~	R156-37-502(3)	$[-]500 - $[-]2,000	$[-]2,500 - $[-]10,000
~~(100)~~	R156-37-502(4)	$[-]500 - $[-]2,000	$[-]2,500 - $[-]10,000
~~(101)~~	R156-37-502(5)	$[-]500 - $[-]2,000	$[-]2,500 - $[-]10,000
~~(102)~~	R156-37-502(6)	$[-]500 - $[-]2,000	$[-]2,500 - $[-]10,000
~~(103)~~	R156-37-502(7)	$[-]500 - $[-]2,000	$[-]2,500 - $[-]10,000
~~(104)~~	R156-37-502(8)	$[-]500 - $[-]2,000	$[-]2,500 - $[-]10,000
	R156-37-502(11)	$500 - $2,000	$2,500 - $10,000
~~(105)~~]	Any other conduct that constitutes [~~U~~]unprofessional or [~~U~~]unlawful conduct	$[-]100 - $[-]500	$[-]200 - $[-]1,000

R156-17b-502. Unprofessional Conduct.

Under Sections 58-1-501 and 58-17b-502, "[~~U~~]unprofessional conduct" includes:

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

(2) (a) failing to comply with the USP-NF <795>, if applicable to activities performed; or

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

(3) failing to comply with continuing education requirements;

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

[~~(5) failing to timely fulfill a subpoena issued under Section R156-1-110;~~]

([~~6~~]5) failing to abide by applicable federal and state law regarding the practice of pharmacy;

([~~7~~]6) failing to comply with administrative inspections;

([~~8~~]7) failing to return a self-audit report by the deadline established by the Division;

([~~9~~]8) providing false information on a self-audit report;

([~~10~~]9)(a) violating the laws and rules regulating operating standards in a pharmacy, as discovered upon inspection by the Division; or

(b) after discovery upon inspection by the Division of violation of laws and rules regulating operating standards in a pharmacy, failing to comply within the time established by the Division;

([~~11~~]10) abandoning a pharmacy or leaving prescription drugs accessible to the public;

([~~12~~]11)(a) as a pharmacist, practicing pharmacy with an inappropriate pharmacist to pharmacy intern ratio under Subsection R156-17b-606(3) or pharmacist to pharmacy technician trainee ratio under Subsection R156-17b-601(4); or

(b) as a pharmacy, practicing pharmacy with an inappropriate pharmacist to pharmacy intern ratio under Subsection R156-17b-606(3) or pharmacist to pharmacy technician trainee ratio under Subsection R156-17b-601(4);

([~~13~~]12)(a) as a pharmacist, allowing an unauthorized person in the pharmacy; or

(b) as a pharmacy, allowing an unauthorized person in the pharmacy;

([~~14~~]13)(a) as a pharmacist, failing to offer to counsel a person receiving a prescription medication; or

(b) as a pharmacy, failing to offer to counsel a person receiving a prescription medication;

([~~15~~]14) failing to timely pay an administrative fine;

([~~16~~]15) failing to comply with the PIC, consulting pharmacist, RDPIC or DMPIC standards under Section R156-17b-603;

([~~17~~]16) failing to adhere to institutional policies and procedures related to technician checking of medications when technician checking is utilized;

([~~18~~]17) failing to take appropriate steps to avoid or resolve identified drug therapy management problems under Subsection R156-17b-611(3);

([~~19~~]18) dispensing medication that has been discontinued by the FDA;

([~~20~~]19) failing to keep or report accurate records of training hours;

([~~21~~]20) failing to provide consulting pharmacist, designated representative, responsible [~~party~~]individual, PIC, RDPIC, or DMPIC information to the Division within 30 days of a change in consulting pharmacist, designated representative, responsible [~~party~~]individual, PIC, RDPIC or DMPIC;

([~~22~~]21) requiring a pharmacy, pharmacist, or DMP to operate the pharmacy or allow the operation of the pharmacy with a ratio of supervising pharmacist or DMP to other pharmacy personnel in circumstances that result in, or reasonably would be expected to result in, an unreasonable risk of harm to public health, safety, and welfare;

([~~23~~]22)(a) as a pharmacist, failing under Subsection R156-17b-603([~~3~~]2)([~~t~~]b) to notify the Division within seven calendar days of a change in the email address designated for use in self-audits or pharmacy alerts; or

(b) as a pharmacy, failing under Subsection R156-17b-603(2)(b) to notify the Division within seven calendar days of a change in the email address designated for use in self-audits or pharmacy alerts;

([~~24~~]23) failing to ensure, as a DMP or DMP clinic pharmacy, that a DMP designee has completed a formal or on-the-job dispensing training program under Section R156-17b-622;

([~~25~~]24) failing to make a timely report regarding dispensing of an opiate antagonist to the Division and to the physician who issued the standing order, under Section R156-17b-625; and

([~~26~~]25) failing to comply with the operating standards for a remote dispensing pharmacy under Section R156-17b-614g.

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

Under Subsection 58-17b-102(57), this section defines practice as a licensed pharmacy technician.

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

(a) receiving written prescriptions;

(b) taking refill orders, including refill authorizations;

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

(d) preparing labels;
(e) retrieving medications from inventory;
(f) counting and pouring into containers;
(g) placing medications into patient storage containers;
(h) affixing labels;
(i) compounding;
(j) counseling for over-the-counter drugs and dietary supplements under the direction of the supervising pharmacist;
(k) receiving new prescription drug orders when communicating telephonically or electronically, if the original information is recorded so the pharmacist may review the prescription drug order as transmitted, including accepting new prescription drug orders saved on voicemail for a pharmacist to review;
(l) transferring prescriptions under [~~Subsections 58-17b-604(4)(a),~~]Sections 58-17b-604[~~,~~] and R156-17b-612;
(m) performing checks of certain medications prepared for distribution, filled or prepared by another technician within a Class B hospital pharmacy, such as medications prepared for distribution to an automated dispensing cabinet, cart fill, crash cart medication tray, or unit dosing from a prepared stock bottle, in accordance with the following operating standards:

(i) a technician authorized by a hospital to check medications shall have at least:

(A) one year of experience working as a pharmacy technician; and

(B) six months of experience at the hospital where the technician is authorized to check medications;

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

(iii) a hospital that authorizes technicians to check medications shall:

(A) have a training program and ongoing competency assessment that is documented and retrievable during each technician's employment and at least three years beyond employment;

(B) maintain a list of technicians on staff [~~that~~]who are allowed to check medications;

(C) have a medication error reporting system and be able to produce documentation of its use;

(D) have a supervising pharmacist immediately available during times [~~that~~]when a pharmacy technician is checking medications; and

(E) have comprehensive policies and procedures that guide technician checking [~~that~~]and include the following:

(I) process for technician training and ongoing competency assessment and documentation;

(II) process for supervising technicians who check medications;

(III) list of medications, or types of medications, that may [~~or may not~~]be checked by a technician;
(IV) description of the automation or technology [~~to be utilized~~]used by the institution to augment the technician check;
(V) process for maintaining a permanent log of the unique initials or identification codes that identify each technician responsible for checked medications by name; and
(VI) description of processes used to track and respond to medication errors; and

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

(2) A pharmacy technician may not:

(a) receive a new prescription or medication order, except as described in Subsection (1)(k);

(b) clarify a prescription or medication order from a prescriber;

(c) perform a drug utilization review;

(d) perform final review of a prescribed drug prepared for dispensing;

(e) dispense a drug; or

(f) counsel a patient [~~with respect to~~]about a prescription drug.

(3) A pharmacy technician may administer vaccines and emergency medications pursuant to delegation by a pharmacist under the Utah Guidance for Vaccine Prescription and Administration[~~Protocol~~], if the pharmacy technician:

(a) has completed the initial training required by Section R156-17b-621;

(b) is under direct, on-site supervision by the delegating pharmacist as defined in Subsection R156-1-102a(1)(a); and

(c) for each renewal cycle after the initial training, has completed a minimum of two hours of continuing education in immunization or vaccine-related topics in accordance with Section R156-17b-309.

(4) A pharmacy technician trainee:

(a) shall practice only under the direct supervision of a pharmacist, and in a ratio not to exceed:

(i) one pharmacy technician trainee to one pharmacist; or

(ii) two pharmacy technician trainees to one pharmacist, if a licensed pharmacy technician or intern is working during the same shift; and

(b) may perform any task in Subsection (1), except performing checks of certain medications prepared for distribution, filled or prepared by a technician within a Class B hospital pharmacy as described in Subsection (1)(m).

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

Under Section R156-17b-606, [~~A~~]a pharmacy intern may provide services including the practice of pharmacy under the supervision of a pharmacist preceptor[~~ in accordance with Section R156-17b-606~~].

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

Under Subsection 58-17b-601(1) and Section 58-17b-612, the duties of the consulting pharmacist, PIC, RDPIC, and DMPIC are established in this section

(1) The consulting pharmacist, PIC, RDPIC, or DMPIC shall: [~~have the responsibility to~~]

(a) oversee the operation of the pharmacy [~~in conformance with laws and rules pertinent to the practice of pharmacy~~]and the distribution of drugs, durable medical equipment, and medical supplies;[~~. The consulting pharmacist, PIC, RDPIC, or DMPIC shall~~]

(b) be personally in full and actual charge of the pharmacy[~~.~~];

(c) ensure that a pharmacist, pharmacy intern, DMP, or DMP designee dispenses drugs or devices, including:

(i) packaging, preparation, compounding, and labeling; and

(ii) ensuring that drugs are dispensed safely and accurately as prescribed;

(d) ensure pharmacy personnel deliver drugs to the patient or the patient's agent safely and accurately as prescribed;

(e) ensure that a pharmacist, pharmacy intern, or DMP communicates to the patient or the patient's agent, at their request, information concerning any prescription drugs dispensed to the patient by the pharmacist, pharmacy intern, or DMP;

(f) ensure that a reasonable effort is made to obtain, record, and maintain patient medication records;

(g) educate and train pharmacy personnel;

(h) establish policies for procurement of prescription drugs and devices and other products dispensed from the pharmacy;

(i) dispose and distribute drugs from the pharmacy;

(j) bulk compound drugs;

(k) ensure appropriate storage of materials, including drugs, chemicals, and biologicals;

(l) maintain records of transactions of the pharmacy necessary to maintain accurate control over and accountability for pharmaceutical materials;

(m) establish and maintain effective controls against theft or diversion of prescription drugs and records for the prescription drugs;

(n) if records are kept on a data processing system, maintain records stored in that system in compliance with pharmacy requirements;

(o) legally operate the pharmacy;

(p) if permitted to use an automated pharmacy system for dispensing purposes under Section R156-17b-620:

(i) ensure that the system is in good working order and accurately dispenses the correct strength, dosage form, and quantity of the drug prescribed while maintaining appropriate recordkeeping and security safeguards; and

(ii) implement an ongoing quality assurance program that monitors performance of the automated pharmacy system, which is evidenced by written policies and procedures developed for pharmaceutical care;

(q) ensure that relevant information is submitted to the Controlled Substance Database in the appropriate format and in a timely manner;

(r) ensure the pharmacy operates with a ratio of pharmacist or DMP to other pharmacy personnel sufficient to prevent circumstances that result in, or would reasonably be expected to result in, an unreasonable risk of harm to public health, safety, and welfare;

(s) ensure the consulting pharmacist, PIC, RDPIC, or DMPIC assigned to the pharmacy is recorded with the Division on a form provided by the Division, and that the Division is notified of a change in consulting pharmacist, PIC, RDPIC, or DMPIC within 30 days of the change; and

(t) under Subsection 58-17b-103(1), conduct a pharmacy self-audit on a form provided by the Division according to the following timeframes:

(i) within 30 days of a change of consulting pharmacist, PIC, DMPIC, or RDPIC;

(ii) within 30 days of the opening of a new facility;

(iii) at least 90 days before the end of each renewal cycle; and

(iv) maintain each pharmacy self-audit form for two years from the date of the self-audit.

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

(b) The consulting pharmacist, PIC, RDPIC, DMPIC, or responsible [~~party~~]individual shall:

(i) notify the Division of the pharmacy's email address in the initial application for licensure;

(ii) use a single email address; and

(iii) notify the Division of a change in the email address within seven calendar days of the change;

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

~~(a) ensuring that a pharmacist, pharmacy intern, DMP, or DMP designee dispenses drugs or devices, including:~~

~~(i) packaging, preparation, compounding and labeling; and~~

~~(ii) ensuring that drugs are dispensed safely and accurately as prescribed;~~

~~(b) ensuring that pharmacy personnel deliver drugs to the patient or the patient's agent, including ensuring that drugs are delivered safely and accurately as prescribed;~~

~~(c) ensuring that a pharmacist, pharmacy intern, or DMP communicates to the patient or the patient's agent, at their request, information concerning any prescription drugs dispensed to the patient by the pharmacist, pharmacy intern, or DMP;~~

~~(d) ensuring that a reasonable effort is made to obtain, record, and maintain patient medication records;~~

~~(e) education and training of pharmacy personnel;~~

~~(f) establishment of policies for procurement of prescription drugs and devices and other products dispensed from the pharmacy;~~

(g) disposal and distribution of drugs from the pharmacy;
(h) bulk compounding of drugs;
(i) storage of materials, including drugs, chemicals, and biologicals;
(j) maintenance of records of transactions of the pharmacy necessary to maintain accurate control over and accountability for pharmaceutical materials required by state and federal laws and regulations;
(k) establishment and maintenance of effective controls against theft or diversion of prescription drugs and records for the prescription drugs;
(l) if records are kept on a data processing system, the maintenance of records stored in that system in compliance with pharmacy requirements;
(m) legal operation of the pharmacy including meeting inspection and other requirements of state and federal laws, rules and regulations governing the practice of pharmacy;
(n) implementation of an ongoing quality assurance program that monitors performance of the automated pharmacy system, which is evidenced by written policies and procedures developed for pharmaceutical care;
(o) if permitted to use an automated pharmacy system for dispensing purposes:
(i) ensuring that the system is in good working order and accurately dispenses the correct strength, dosage form and quantity of the drug prescribed while maintaining appropriate record keeping and security safeguards; and
(ii) implementation of an ongoing quality assurance program that monitors performance of the automated pharmacy system, which is evidenced by written policies and procedures developed for pharmaceutical care;
(p) ensuring that relevant information is submitted to the Controlled Substance Database in the appropriate format and in a timely manner;
(q) ensuring that pharmacy personnel have the appropriate licensure;
(r) ensuring that no pharmacy operates with a ratio of pharmacist or DMP to other pharmacy personnel in circumstances that result in, or reasonably would be expected to result in, an unreasonable risk of harm to public health, safety, and welfare;
(s) ensuring that the consulting pharmacist, PIC, RDPIC, or DMPIC assigned to the pharmacy is recorded with the Division on a form provided by the Division, and that the Division is notified of a change in consulting pharmacist, PIC, RDPIC, or DMPIC within 30 days of the change;
(t) ensuring, with regard to the unique email address used for self-audits and pharmacy alerts, that the pharmacy:
(i) uses a single email address; and
(ii) notifies the Division, on the form prescribed, of a change in the email address within seven calendar days of the change;
(u) under Subsection 58-17b-103(1), conducting a pharmacy self-audit on a form provided by the Division, in accordance with the following timeframes:
(i) within 30 days of a change of consulting pharmacist, PIC, DMPIC or RDPIC;

~~(ii) within 30 days of the opening of a new facility; and~~
~~(iii) at least 90 days before the end of each renewal cycle; and~~
~~(iv) maintaining each pharmacy self-audit form for two years from the date of the self-audit.~~]

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

Under Subsections 58-17b-601(1) and 58-17b-614(1)(a)(i), the requirements for closing a pharmacy are established in this section.

(1) The consulting pharmacist, DR, [~~R~~]responsible [~~party~~]individual, PIC, RDPIC, or DMPIC of the registered pharmacy shall comply with 21 CFR 1301.52 (2021) and 21 CFR 1305.18 and 1305.19 (2021).

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

(a) the date of closing; and

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

(3) On the date of closing, the consulting pharmacist, PIC, RDPIC, or DMPIC shall remove prescription drugs from the pharmacy by [~~one or a combination~~]any of the following methods:

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

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

(4) If the pharmacy dispenses prescription drug orders:

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

(b) move signs or notify the landlord or owner of the property that it is unlawful to use the word "pharmacy", or any other word or combination of words of the same or similar meaning, or any graphic representation that would mislead or tend to mislead the public that a pharmacy is located at this address, unless the use is permitted under the exception defined in Subsection R156-17b-102(72).

(5) Within ten days of the closing of the pharmacy, the pharmacy owner, consulting pharmacist, DR, [~~R~~]responsible [~~Party~~]individual, PIC, RDPIC, or DMPIC shall forward to the Division a surrender notice, on a form provided by the Division, [~~of the closing~~]that includes the following information:

(a) the actual date of closing;

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

(c) a statement attesting:

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

(ii) the [~~manner in which~~]method used to transfer or dispose of the legend drugs and controlled substances possessed by the pharmacy[~~ were transferred or disposed~~]; and

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

(6) [~~If the pharmacy is closed suddenly due to fire, destruction, natural disaster, death, property seizure, eviction, bankruptcy or other emergency circumstances and the consulting pharmacist, DR, Responsible Party, PIC, RDPIC, or DMPIC cannot provide notification 14 days prior to the closing, the consulting pharmacist, PIC, RDPIC, or DMPIC shall comply with Subsection (1) as far in advance of the closing as allowed by the circumstances.~~]If the consulting pharmacist, DR, responsible individual, PIC, RDPIC, or DMPIC cannot provide notification 14 days prior to the closing due to an emergency circumstance, such as fire, destruction, natural disaster, death, property seizure, eviction, or bankruptcy, they shall comply with Subsection (1) as far in advance of the closing as allowed by the circumstances.

(7) If the consulting pharmacist, DR, [~~R~~]responsible [~~Party~~]individual, PIC, RDPIC, or DMPIC is not available to comply with the requirements of this section, the owner or legal representative shall be responsible for compliance with this section.

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

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

Under Subsection 58-17b-601(1), the requirements for inventory of a pharmacy are established in this section.

(1) Authorized personnel shall remove out-of-date legend drugs and controlled substances from the inventory at regular intervals and [~~in correlation~~]according to the beyond use date imprinted on the label.

(2) General requirements for inventory of a pharmacy [~~shall~~]include the following:

(a) the consulting pharmacist, PIC, RDPIC, or DMPIC shall be responsible for taking required inventories, but may delegate the performance of the inventory to another person;

(b) the inventory records shall be:

(i) maintained for a period of five years;[~~ and be~~]

(ii) readily available for inspection;

[~~(c) the inventory records shall be~~](iii) filed separately from all other records; and

[~~(d) the inventory records shall be~~](iv) in a written, typewritten, or printed form and include each stock of controlled substances on hand on the date of the inventory, including any [~~that are~~]out-of-date drugs and drugs in automated pharmacy systems;

([~~e~~]c) an inventory taken by use of a verbal recording device shall be promptly transcribed;

([~~f~~]d) the inventory may be taken either at[~~s~~] the opening of the business or the close of business on the inventory date;

([~~g~~]e) the [~~person~~]individual taking the inventory and the consulting pharmacist, PIC, RDPIC, or DMPIC shall state the time the inventory was taken and shall sign and date the inventory with the date the inventory was taken;

([~~h~~]f) the signature of the consulting pharmacist, PIC, RDPIC, or DMPIC and the date of the inventory shall be documented within 72 hours or three working days of [~~the~~]a completed initial, annual, change of ownership, [~~and~~]or closing inventory;

([~~i~~]g) the [~~person~~]individual taking the inventory shall make an exact count or measure of Schedule I or II controlled substances[~~ listed in Schedule I or II~~];

([~~j~~]h) the [~~person~~]individual taking the inventory shall make an estimated count or measure of Schedule III, IV, or V controlled substances, but if the container holds more than 1,000 tablets or capsules, an exact count of the contents shall be made;

([~~k~~]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; and

([~~l~~]j) if the pharmacy maintains a perpetual inventory of any of the drugs required to be inventoried, the perpetual inventory shall be reconciled on the date of the inventory.

(3) Requirements for taking the initial controlled substances inventory shall include the following:

(a) pharmacies having stock of controlled substances shall take an inventory, including out-of-date drugs and drugs in automated pharmacy systems, on the opening day of business;

(b) (i) if a pharmacy commences business with no Schedule I or II controlled substances, the pharmacy shall record this fact as the initial inventory; and

(ii) if a pharmacy commences business with no Schedule III, IV, and V controlled substances, the pharmacy shall document Schedule I and II controlled substance inventory separately from an inventory reporting no Schedule III, IV, and V controlled substances;

(c) the initial inventory shall serve as the pharmacy's inventory until the next completed inventory as specified in Subsection (4) of this section; and

(d) when combining two closing 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 before opening.

(4) [~~Requirement for~~]Each annual controlled substances inventory:

(a) shall be within 12 months following the inventory date of each year;[~~and~~]

(b) may be taken within four days of the specified inventory date; and

(c) shall include stocks including out-of-date drugs and drugs in automated pharmacy systems.

(5) Requirements for a qualifying change of ownership shall include the following:

(a) the pharmaceutical facility shall take an inventory of legend drugs and controlled substances, including out-of-date drugs and drugs in automated pharmacy systems, on the date of the qualifying change of ownership;
(b) such inventory shall constitute the closing inventory for the seller and the initial inventory for the buyer; and
(c) any transfer of Schedule I and II controlled substances shall [~~require the~~]use [~~of~~]official DEA order form 222.

(6) A pharmacy shall maintain a perpetual inventory of Schedule II controlled substances that shall be reconciled according to facility policy.

R156-17b-608. Delivery Via United States Postal Service, Licensed Common Carrier, or Supportive Personnel.

(1) Under Subsection 58-17b-601(1), a[~~A~~] pharmacy that employs the United States Postal Service, common carrier, or supportive personnel to deliver a filled prescription to a patient shall:

(a) use adequate storage or shipping containers and shipping processes to ensure drug stability and potency and appropriate storage temperatures throughout delivery with packaging material and devices recommended by the manufacturer or the United States Pharmacopeia Chapter 1079;
(b) use shipping containers sealed in a manner to detect evidence of opening or tampering;
(c) have policies and procedures to ensure accountability, safe delivery, and compliance with temperature requirements, including when drugs do not arrive on time or there is evidence that the integrity of a drug was compromised and providing for the replacement of those drugs;
(d) provide for an electronic, telephonic, or written communication mechanism to offer counseling to the patient in accordance with Sections 58-17b-613 and R156-17b-610; and
(e) provide information to the patient indicating what the patient should do if the integrity of the packaging or drug was compromised during shipment.

(2) Under Subsection 58-17b-503(2)(c)(iii), to determine that a drug has not been adversely affected by the drug's attempted delivery and return, before the drug is redistributed the pharmacist at the pharmacy shall:

(a) verify that the drug was returned to the original pharmacy within 14 days of the shipped date;
(b) determine in the pharmacist's clinical judgment that the drug's integrity is intact and the security of the drug packaging has not been compromised; and
(c) if the drug is a controlled substance, correct the report to the Controlled Substance Database.

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

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

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

(2) A hospital pharmacy may delete a patient profile for an inpatient upon discharge if a record of prescriptions is maintained as part of the hospital record.

(3) A responsible pharmacist or DMP at the pharmacy shall determine the information included in a patient profile, but shall include at least the following patient information:

(a) first and last name;
(b) address;
(c) telephone number;
(d) date of birth or age;
(e) gender;
(f) patient history where significant, including known allergies and drug reactions;
(g) a list of any prescription drugs obtained by the patient at the pharmacy, including:
(i) name of the prescription drug;
(ii) strength of the prescription drug;
(iii) quantity dispensed;
(iv) date of filling or refilling; and
(v) charge for the prescription drug as dispensed to the patient; and
(h) any additional comments relevant to the patient's drug use.

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

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

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

~~(i) name of prescription drug;~~
~~(ii) strength of prescription drug;~~
~~(iii) quantity dispensed;~~
~~(iv) date of filling or refilling;~~
~~(v) charge for the prescription drug as dispensed to the patient; and~~
~~(c) any additional comments relevant to the patient's drug use.~~]

([~~3~~]4) Patient medication profile information shall be recorded by a pharmacist, pharmacy intern, pharmacy technician, pharmacy technician trainee, or DMP designee.

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

Under Subsection 58-17b-601(1) and Section 58-17b-613, this section establishes guidelines for providing patient counseling.

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

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

(2) A pharmacy facility shall verbally offer the patient or patient's agent counseling as described in Subsection (1)[~~,~~] but is not required to provide counseling to a patient or patient's agent who refuses 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) the intended use of the drug, when known, and expected action;

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

(e) any 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) the techniques for self-monitoring drug therapy;

(g) the proper storage;

(h) the prescription refill information;

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

(j) any 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)[~~(a)~~] The offer to counsel shall be documented and such documentation shall be maintained for five years, available for inspection upon Division request within seven to ten business days.

[~~(b) Any documentation shall be maintained for five years, and be available for inspection by the Division within seven to ten business days of the Division's request.~~]

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

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

(~~a~~) the pharmacy shall provide for an electronic, telephonic, or written communication mechanism to deliver the information in Subsection (3)[~~ shall be delivered with the dispensed prescription in writing~~];

(b) the information under Subsection (6)(a) shall be in a form similar to USP-NF patient information monographs or equivalent information; and

([~~b~~]c) 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 i~~]Information about this prescription has been provided for you. Please read this information before you take this medication. If you have questions concerning this prescription, a pharmacist is available during normal business hours to answer these questions."[~~; and~~

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

(7) Patient counseling is not required for patients of a hospital or institution where:

(a) other licensed health care professionals are authorized to administer the patient's drugs[.]; or

(b) any unused portion of facility-provided medication is offered to the patient under Section 26B-4-516.

(8) A pharmacist or pharmacy intern who dispenses a self-administered hormonal contraceptive shall:

(a) obtain a completed Utah Hormonal Contraceptive Self-Screening Risk Assessment Questionnaire which can be found on the Division's website at https://[dopl]commerce.utah.gov/dopl/pharmacy/resources/; and

(b) provide any other written information and counseling as described in Section 26B-4-506.

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

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

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

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

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

~~(b) a Naloxone kit.~~

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

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

~~(b) patient's name;~~

~~(c) name of medication and strength;~~

~~(d) date given;~~

~~(e) instructions for use; and~~

~~(f) beyond use date.~~

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

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

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

(1) The prescription drug shall be dispensed:

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

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

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

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

(b) patient's name;

(c) name and strength of medication;
(d) date given;
(e) instructions for use; and
(f) beyond use date.

(3) To meet a patient's immediate needs, the prescribing practitioner may provide up to a three-day emergency supply, which is properly labeled according to Subsection R156-17b-610.6(2).

(4) Notwithstanding Subsection R156-17b-610.6(3), the following may be provided:

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

(b) a Naloxone kit.

([~~3~~]5) Applicable data of controlled substances dispensed shall be reported to the Utah Controlled Substance Database.

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

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

(a) date;
(b) quantity supplied; and
(c) quantity remaining of the prescription partially filled.

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

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

(a) implementing, modifying, and managing drug therapy according to the terms of the Collaborative Pharmacy Practice Agreement;
(b) collecting and reviewing patient histories;
(c) obtaining and checking vital signs, including pulse, temperature, blood pressure, and respiration;
(d) ordering and evaluating the results of laboratory tests directly applicable to the drug therapy, when performed [~~in accordance with~~]according to approved protocols applicable to the practice setting; and
(e) [~~such~~]other patient care services [~~as may be~~]allowed by rule.

(2) [~~For the purpose of promoting therapeutic appropriateness, a~~]A pharmacist engaging in drug therapy management shall, at the time of dispensing a prescription[,] or a prescription drug order, review the patient's medication record[~~. Such review shall at a minimum~~] and identify any clinically significant conditions, situations, or items, such as:

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

(g) clinical abuse or misuse.

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

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

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

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

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

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

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

(5) [~~In accordance with~~]Under Section 58-17b-604, prescriptions for legend drugs [~~having~~]that have a remaining authorization for refill may be transferred from the pharmacy holding the prescription to another pharmacy upon the authorization of the patient to whom the prescription was issued, including electronic authorization under Subsection R156-17b-613(8).

(6) Under Section 58-17b-604, prescriptions for legend drugs that have a remaining authorization for refill may be transferred by a:

(a) [~~the~~] pharmacist[~~,~~];

(b) pharmacy intern[~~,~~];

(c) pharmacy technician, at the discretion of the pharmacist on duty[~~,~~]; or

(d) DMP at the pharmacy holding the prescription[~~to a pharmacist, pharmacy intern, pharmacy technician, or DMP at another pharmacy upon the authorization of the patient to whom the prescription was issued or electronically as authorized under Subsection R156-17b-613(9)~~].

(7) (a) The transferring pharmacist, pharmacy intern, or DMP and receiving pharmacist, pharmacy intern, or DMP shall:

(i) act diligently to ensure that the total number of authorized refills is not exceeded;[~~. The following additional terms apply to such a transfer:~~]

([~~a~~]ii) ensure the transfer [~~shall be~~]is communicated directly between pharmacists, pharmacy interns, pharmacy technicians, or DMPs or as authorized under Subsection R156-17b-613([~~9~~]8);

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

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

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

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

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

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

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

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

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

(E) [~~the~~]name of the pharmacist, pharmacy intern, or DMP [~~transferring~~]who transferred the prescription[~~- drug order information~~];

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

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

([~~6~~]8) Prescriptions for terminal patients in licensed hospices, home health agencies, or nursing homes may be partially filled if the patient has a medical diagnosis documenting a terminal illness and may not need the full prescription amount.

([~~7~~]9) Refills may be dispensed only in accordance with the prescriber's authorization as indicated on the original prescription drug order.

([~~8~~]10) Additional authorization from the prescribing practitioner shall be obtained prior to dispensing any refills if:

(a) there are no refill instructions on the original prescription drug order; or

(b) refills authorized on the original prescription drug order have been dispensed.

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

([~~9~~]11) Refills of prescription drug orders for legend drugs may not be refilled after [~~one~~]two years from the date of issuance of the original prescription drug order without obtaining authorization from the prescribing practitioner prior to dispensing any additional quantities of the drug.

([~~10~~]12) Refills of prescription drug orders for controlled substances shall be done in accordance with Subsections 58-37-[~~6(7)(f)~~]304(5) through (6).

([~~11~~]13) A pharmacist or DMP may exercise professional judgment in refilling a prescription drug order for a drug[~~, other than a Schedule II controlled substance,~~] without the authorization of the prescribing practitioner, if:

(a) the drug is not a Schedule II controlled substance;

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

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

([~~c~~]d) either:

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

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

([~~d~~]e) if the prescription was originally filled at another pharmacy:

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

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

([~~e~~]f) the pharmacist or DMP:

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

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

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

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

([~~12~~]14) The address specified in Subsection 58-17b-602(1)(b) shall be a physical address, not a post office box.

([~~13~~]15) [~~In accordance with~~]Under Subsection 58-37-[~~6(7)(e)~~]304(5), a prescription may not be written, issued, filled, or dispensed for a Schedule I controlled substance unless:

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

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

([~~14~~]16) A pharmacist or pharmacy intern may dispense an emergency refill prescription for a drug a patient is currently using and on file with the pharmacy, other than a controlled substance, without the prescribing practitioner's authorization if they are not available promptly, in accordance with Section 58-17b-608, for:

(a) a 30[-]-day supply with the prescribing practitioner's instructions; or

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

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

(1) [~~In accordance with~~]Under Subsection[~~s~~] 58-17b-601(1) and Sections 58-17b-610.8 and 58-17b-627, the operating standards for prescription devices are established in this section.

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

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

(a) an appropriate dispense quantity;

(b) directions for device use; and

(c) refill.

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

(a) [~~dispensed~~]in accordance with Subsections 58-17b-602(1)(a) through (e) and Section 58-17b-609; and

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

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

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

(i) pharmacy name;

(ii) pharmacy phone number;

(iii) patient name;

(iv) dispensed quantity;

(v) directions for use; and

(vi) refill.

R156-17b-612b. Operating Standards - Insulin Prescription and Diabetes Supplies.

(1) Under Subsection 58-17b-601(1) and Section 58-17b-608.2, the operating standards for dispensing an exhausted prescription for insulin are as follows:

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

(b) The pharmacist [~~who dispenses~~]dispensing a refill of an exhausted prescription of insulin shall obtain:

(i) the prescribing information for the insulin;

(ii) prescription directions; and

(iii) other documentation based on the pharmacist's clinical judgment.

(c) The pharmacist shall document the following on the exhausted prescription refill hard copy or in the medication profile system:

(i) the information described in Subsection (1)(b);

(ii) the method of the attempt [~~under Subsection 58-17b-608.2(5)(a) ~~]to contact the patient's prescribing practitioner under Subsection 58-17b-608.2(5)(a); and

(iii) the method of the notification to the patient under Subsection 58-17b-608.2(5)(b) regarding the outcome of the attempt to contact the prescribing practitioner.

(d) An exhausted prescription refill label shall state "exhausted prescription."

(2) Under Subsection 58-17b-608.2(7)(f), a pharmacist may dispense a therapeutic equivalent when filling a prescription for supplies for treating diabetes that are listed in the Utah Guidance for Diabetic Therapeutic Equivalents posted on the Division's website at https://[~~dopl~~]commerce.utah.gov/dopl/pharmacy/resources/.

R156-17b-612c. Operating Standards -- Therapeutically Similar Drug Products.

(1) Under Subsection 58-17b-605(9)(a), [T]the Division shall maintain the Therapeutically Similar Drug List posted [~~list of therapeutically similar drug products under Subsection 58-17b-605(9)(a) ~~]on the Division's website at https://[~~dopl~~]commerce.utah.gov/dopl/pharmacy/resources/.

(2) The Division may not add or remove a therapeutically similar drug product from the list without specific resolutions, passed by both the Board and the Medical Licensing Board, stating that they do not object to the addition or removal of the therapeutically similar drug.

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

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

(1) Prescription orders for Schedule II [-]through V controlled substances received by electronic communication shall be handled according to 21 CFR 1304.06 (2021).

(2) Prescription orders for non-controlled substances received by electronic communication may be dispensed by a pharmacist, pharmacy intern, or DMP only if the following conditions are satisfied:

(a) Electronically transmitted prescription orders shall include the following:

(i) information that is required to be contained in a prescription order pursuant to Section 58-17b-602;

(ii) the time and date of the transmission, and if a facsimile transmission, the electronically encoded date, time, and fax number of the sender; and

(iii) the name of the pharmacy intended to receive the transmission.

(b) A prescription order shall be transmitted under the direct supervision of the prescribing practitioner or the prescribing practitioner's designated agent.

(c) The pharmacist or DMP shall exercise professional judgment regarding the accuracy and authenticity of the transmitted prescription.

(d) A practitioner or the practitioner's agent shall provide voice verification when requested by the pharmacist receiving a [~~medication~~]prescription order.

(e) The pharmacist, pharmacy intern, pharmacy technician at the discretion of the pharmacist on duty, or DMP shall:

(i) [~~assure~~]ensure that each electronically transferred prescription order is valid; and

(ii) [~~shall~~]authenticate a prescription order issued by a prescribing practitioner that has been transmitted to the dispensing pharmacy before filling it[~~,~~] whenever there is a question about the prescription order.

(f)[(~~i~~)] A practitioner may authorize an agent to electronically transmit a prescription if the agent's identifying information is on the transmission.

([~~ii~~]g) The practitioner's electronic signature, or other secure method of validation, shall be provided with the electronic prescription.

(3) [~~a~~]An electronically transmitted prescription order that meets the requirements of Subsection (2) shall be the original prescription.

[~~(4) This section does not apply to the use of electronic equipment to transmit prescription orders within inpatient medical facilities.~~]

[~~(5) An agreement between a prescribing practitioner and a pharmacy may not require that prescription orders be transmitted by electronic means from the prescribing practitioner only to that pharmacy.~~]

([~~6~~]4) The pharmacist or DMP shall retain a legible printed copy of an electronic prescription, or a record of an electronic prescription that is readily retrievable and printable, for a minimum of five years.[~~The printed copy shall be of non-fading legibility.~~]

(5) An agreement between a prescribing practitioner and a pharmacy may not require that prescription orders be transmitted by electronic means from the prescribing practitioner only to that pharmacy.

(6) An electronically transmitted prescription order shall be transmitted to the pharmacy of the patient's choice.

(7) Wholesalers, distributors, manufacturers, pharmacists, and pharmacies may not supply electronic equipment to a prescriber for transmitting prescription orders.

[~~(8) An electronically transmitted prescription order shall be transmitted to the pharmacy of the patient's choice.~~]

([~~9~~]8) Prescription orders electronically transmitted to the pharmacy by the patient may not be filled or dispensed.

([~~10~~]9) A prescription order for a legend drug or controlled substance in Schedule III through V may be transferred up to the maximum refills permitted in accordance with 21 CFR 1306.22 (2021) or by the prescriber by electronic transmission, if:

(a) the pharmacies share a real-time, online database;

(b) the information required to be on the transferred prescription has the same information described in Subsection R156-17b-612([~~5~~]7)[~~(a) through (f)~~]; and

(c) pharmacists, pharmacy interns, pharmacy technicians, [~~or~~]pharmacy technician trainees, DMPs, and DMP designees electronically accessing the same prescription drug order records may electronically transfer prescription information if the data processing system has a mechanism to send a message to the transferring pharmacy containing the following information:

(i) the fact that the prescription drug order was transferred;

(ii) the unique identification number of the prescription drug order transferred;

(iii) the name of the pharmacy to which it was transferred; and

(iv) the date and time of the transfer.

(10) This section does not apply to the use of electronic equipment to transmit prescription orders within inpatient medical facilities.

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

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

(1) [~~The general operating standards include~~]A facility shall:

(a) [~~A facility shall~~]be well-lit[~~lighted~~], well ventilated, clean, and sanitary[~~.~~];

(b) [~~A facility that~~]if the facility transfers a drug from a manufacturer's or distributor's original container to another container, [~~shall~~]have a sink with hot and cold culinary water separate [~~and apart~~]from restroom facilities and any clean rooms where sterile products are prepared; [~~. This sink requirement does not apply to clean rooms where sterile products are prepared. Clean rooms may not have sinks or floor drains.~~]

(c) maintain [~~R~~]required equipment [~~shall be~~]in clean and [~~in~~]good operating condition;[~~.~~]

(d) [~~A facility shall~~]be equipped to store prescription drugs and durable medical equipment:

(i) in an orderly manner that permits clear identification, separation, and easy retrieval of products; and

(ii) in an environment necessary to maintain the integrity of the product inventory;[~~.~~]

(e) [~~A facility shall~~]be equipped to permit practice within the standards and ethics of the profession as dictated by the [~~usual and ordinary~~]scope of practice conducted within that facility;[~~.~~]

(f) [~~A facility shall~~]be stocked with the quality and quantity of product necessary [~~for the facility~~]to meet its scope of practice in a manner consistent with [~~the~~] public safety;[~~.~~]

(g) [~~A~~]if the facility [~~that~~]dispenses controlled substances, [~~shall~~]be equipped with a security system that:

(i) [~~permits detection of~~]detects entry at all times when the facility is closed; and

(ii) provides notice of unauthorized entry to an individual;

(h) [~~A~~]for a pharmacy department, if applicable[shall]:

(i) [~~be equipped~~]equip the department with a lock where drugs are stored; and

(ii) [~~be~~]ensure it is securely locked when the pharmacy department is closed[~~.~~];

(i) [~~A facility shall~~]have a counseling area to allow for confidential patient counseling, if applicable[~~.~~];

(j) have current editions of the following reference publications in print or electronic format readily available to and retrievable by facility personnel:
(i) Title 58, Chapter 1, Division of Professional Licensing Act;
(ii) Rule R156-1, General Rule of the Division of Professional Licensing;
(iii) Title 58, Chapter 17b, Pharmacy Practice Act;
(iv) Rule R156-17b, Pharmacy Practice Act Rule;
(v) Title 58, Chapter 37, Utah Controlled Substances Act;
(vi) Rule R156-37, Utah Controlled Substances Act Rule;
(vii) Title 58, Chapter 37f, Controlled Substance Database Act;
(viii) Rule R156-37f, Controlled Substance Database Act Rule;
(ix) 21 CFR 1300 et seq. (2021) or equivalent, such as the USP DI Drug Reference Guides;
(x) current FDA-Approved Drug Products; and
(xi) any other general drug references necessary to permit practice, as dictated by the scope of practice conducted within the facility;
(k) maintain a current paper or electronic list of licensed employees involved in the practice of pharmacy at the facility that is readily retrievable for inspection by the Division and includes each licensee's:
(i) first and last names;
(ii) license classification;
(iii) license number; and
(iv) license expiration date;
(l) maintain:
(i) copy 3 of DEA order form 222 that has been properly dated, initialed, and filed;
(ii) copies of each unaccepted or defective order form; and
(iii) any attached statements or other documents;
(m) maintain a record of suppliers' credit memos for controlled substances; and
(n) maintain hard copy reports of surrender or destruction of controlled substances and legend drugs submitted to appropriate state or federal agencies.

(2) (a) Prescription labels for compounded sterile and non-sterile medications, when dispensed to the patient or patient's agent, shall include:
(i) the minimum information required under Section 58-17b-602;
(ii) generic name;
(iii) quantity or concentration of each active ingredient; and
(iv) labeling for sterile preparation for parenteral use shall include:
(A) the name of the diluent;
(B) assigned compounding record or lot number; and
(C) the phrase "compounded preparation."

(b) The requirements described in Subsections (2)(a)(i) and (2)(a)(iv) shall not apply to a label on the container of a drug that a health care provider administers to a patient at:
(i) a pharmaceutical administration facility; or
(ii) a hospital licensed under Title 26B, Chapter 21, Part 2, Health Care Facility Licensing and Inspection[~~Act~~].

(3) The temperature of the pharmacy shall be maintained within a range compatible with the proper storage of drugs. [-]If a refrigerator or freezer is necessary to properly store drugs at the pharmacy, the pharmacy shall keep a daily written or electronic log of the temperature of the refrigerator or freezer on days of operation. The pharmacy shall retain each log entry for at least three years.

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

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

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

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

~~(d) Rule R156-17b, Utah Pharmacy Practice Act Rule;~~

~~(e) Title 58, Chapter 37, Utah Controlled Substances Act;~~

~~(f) Rule R156-37, Utah Controlled Substances Act Rule;~~

~~(g) Title 58, Chapter 37f, Controlled Substance Database Act;~~

~~(h) R156-37f, Controlled Substance Database Act Rule;~~

~~(i) 21 CFR 1300 et seq. (2021) or equivalent such as the USP DI Drug Reference Guides;~~

~~(j) current FDA-Approved Drug Products; and~~

~~(k) any other general drug references necessary to permit practice, as dictated by the usual and ordinary scope of practice conducted within that facility.~~

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

~~(i) individual licensee names;~~

~~(ii) license classifications;~~

~~(iii) license numbers; and~~

~~(iv) license expiration dates.~~

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

([~~6~~]4) A pharmacy may not dispense a prescription drug or device to a patient unless a pharmacist or DMP is physically present and immediately available in the facility, or, for a remote dispensing pharmacy, physically present and immediately available in the facility or supervising through a telepharmacy system.

([~~7~~]5) Only a licensed Utah pharmacist, DMP, or authorized personnel shall have access to the pharmacy when the pharmacy is closed.

([~~8~~]6) The facility or parent company shall maintain a record for at least five years of the initials or identification codes that identify each dispensing pharmacist or DMP by name. [-]The initials or identification code shall be unique to ensure that each pharmacist or DMP can be identified[~~; therefore identical initials or identification codes may not be used~~].

[~~(9) The pharmacy facility shall maintain:~~

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

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

~~(c) any attached statements or other documents.~~]

([~~10~~]7) If applicable, a hard copy of a power of attorney authorizing a pharmacist, DMP, or DMP designee to sign DEA order form 222 shall be available to the Division upon request.

([~~11~~]8) A pharmacist, DMP, or other responsible individual shall verify that controlled substances are listed on the suppliers' invoices and were [~~actually~~]received[~~,~~] by clearly recording their initials and the actual date of receipt of the controlled substances.

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

([~~13~~]9) A copy of the inventories required under Section R156-17b-605 shall be made available to the Division upon request[~~when requested~~].

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

([~~15~~]10) If the pharmacy does not store drugs in a locked cabinet and has a drop or false ceiling, the pharmacy's perimeter walls shall extend to the hard deck, or the pharmacy shall take other measures to prevent unauthorized entry into the pharmacy.

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

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

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

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

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

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

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

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

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

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

(4) The application shall include the following:

(a) complete identifying information [~~concerning~~]for the applying parent pharmacy;

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

(c) address and description of the facility [~~in which~~]where the branch pharmacy [~~is to~~]would be located;
(d) specific formulary to be stocked indicating [~~with respect to each prescription drug,~~] the name, [~~the~~]dosage strength, and dosage units in which the drug will be prepackaged for each prescription drug;
(e) complete identifying information [~~concerning~~]for each [~~person~~]individual [~~located~~]at the branch pharmacy who will dispense prescription drugs [~~in accordance with~~]according to the approved protocol; and
(f) [~~protocols under which~~]the branch pharmacy [~~will~~]operating[~~e~~] protocols and its relationship with the parent pharmacy including[~~to include the following~~]:
(i) [~~the conditions under which~~]how prescription drugs will be stored, used, and accounted for;
(ii) [~~the method by which~~]how the drugs will be transported from the parent pharmacy to the branch pharmacy[~~ and accounted for by the branch pharmacy~~]; and
(iii) a description of how records will be kept with respect to:
(A) formulary;
(B) changes in formulary;
(C) record of drugs sent by the parent pharmacy;
(D) record of drugs received by the branch pharmacy;
(E) record of drugs dispensed;
(F) periodic inventories; and
(G) any other record contributing to an effective audit trail [~~with respect to~~]for prescription drugs provided to the branch pharmacy.

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

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

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

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

(3) (a) A licensed prescribing practitioner [~~Prescriptions for patients in the facility~~]may [~~be~~]verbally request[~~ed~~] prescriptions for patients in the facility [~~by a licensed prescribing~~

~~practitioner ~~]and the request may be entered as the prescribing practitioner's order if the practitioner signs [~~; but the practitioner must personally sign ~~]the order in the facility record within:

(i) 72 hours if prescribing a Schedule II controlled substance; and

(ii) [~~within ~~]30 days if prescribing any other prescription drug.

(b) The prescribing practitioner's verbal order may be copied and forwarded to a pharmacy for dispensing and may serve as the pharmacy's record of the prescription order.

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

(5) [~~Requirements for emergency drug kits shall include:~~

~~(a) a~~]An emergency drug kit may be used by pharmaceutical administration facilities and is subject to the following requirements:[~~.~~]

(a) [~~T~~]the emergency drug kit shall be considered [~~to be ~~]a physical extension of the pharmacy supplying the emergency drug kit and shall remain under the ownership of that pharmacy;

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

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

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

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

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

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

(ii) the emergency kit is locked; and

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

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

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

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

(2) A nuclear pharmacy shall[~~ have the following~~]:

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

(b) have adequate space and equipment [~~commensurate with~~]for the scope of services required and provided[~~.~~];

(c) only dispense radiopharmaceuticals that comply with acceptable standards of quality assurance; and

(d) maintain a library proportional to the level of radiopharmaceutical service provided.

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

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

([~~5~~]3) (a) A licensed Utah pharmacist shall be immediately available on the premises at any time when the facility is open or available to engage in the practice of pharmacy.

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

([~~6~~]4) This [~~rule~~]section does not prohibit:

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

(b) a Utah Radioactive Materials licensee from possessing and using radiopharmaceuticals for medical use.

([~~7~~]5) A hospital nuclear medicine department or an office of a physician-surgeon, osteopathic physician-surgeon, veterinarian, podiatric physician, or dentist that has a current Utah Radioactive Materials License does not require licensure as a Class B pharmacy.

([~~8~~]6) A nuclear pharmacy preparing sterile compounds shall follow the USP-NF Chapter 797 Compound for sterile preparations.

([~~9~~]7) A nuclear pharmacy preparing medications for a specific person shall be licensed as a Class B [~~–~~]nuclear pharmacy if located in Utah, and as a Class D pharmacy if located outside of Utah.

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

Under Subsection 58-17b-601(1) and Section 58-17b-618, the operating standards and requirements for compounding are as follows:

(1) A licensee engaging in sterile or nonsterile compounding shall practice [~~in accordance with~~]according to applicable federal and state laws and rules[~~,~~] and [~~in accordance with~~]the USP-NF, including:

(a) (i) USP <797> Pharmaceutical Compounding - Sterile Preparations;

(ii) except that a smoke study is required only on new construction of a facility, or if physically moving equipment within the clean room;

(b) USP <795> Pharmaceutical Compounding - Nonsterile Preparations; and

(c) USP <825> Radiopharmaceuticals - Preparation, Compounding, Dispensing, and Repackaging.

(2) These operating standards shall apply:

(a) to any pharmacy or individual licensed under Title 58, Chapter 17b, Pharmacy Practice Act, that engages in compounding; and

(b) to the compounding of all sterile or nonsterile compounded pharmaceuticals, antineoplastic drugs, or non-antineoplastic drugs, [~~no matter~~]regardless of where the patient is located.

[~~(3) On or before December 31, 2025, a licensed pharmacy engaging in sterile or nonsterile hazardous drug compounding with antineoplastic drugs according to the NIOSH list under USP <797> and USP <795>, shall practice in accordance with applicable federal and state laws and rules, and in accordance with the requirements of USP <800>, Hazardous Drugs - Handling in Healthcare Settings listed in Subsection (4).~~]

([4]3) A licensed pharmacy compounding sterile or non-sterile non-antineoplastic hazardous drugs shall:

(a) compound sterile or nonsterile hazardous non-antineoplastic drugs in:

(i) a double-HEPA filtered or externally vented containment ventilated exposure (CVE);

(ii) a class II biological safety cabinet (BSC);

(iii) a compounding aseptic containment isolator (CACI);[~~or~~]

(iv) a laminar airflow workbench (LAFW)[~~,~~]; or

(v) a compounding aseptic isolator (CAI) [~~may be used for the compounding of non-antineoplastic HD in accordance with~~]subject to a hazardous drug risk assessment as defined in USP <800> Section 2 Box 1;

(b)[~~(i)~~] clearly mark and identify hazardous API;

(c) store hazardous API in a designated area that is separate from all other medications; and

[~~(ii) (A) store it in a designated area separate from all other medications;~~

~~(B) the designated area does not require a separate room;~~]

([~~c~~]d) adhere to the requirements in USP <800> except the following [~~S~~]sections:

(i) 1. INTRODUCTION AND SCOPE;

(ii) 3. TYPES OF EXPOSURE;

(iii) 5. FACILITIES AND ENGINEERING CONTROLS;

(iv) 6. ENVIRONMENTAL QUALITY AND CONTROL;

(v) 14. ADMINISTERING;

(vi) 16. SPILL CONTROL;

(vii) 17. DOCUMENTATION AND STANDARD OPERATING PROCEDURES, as follows:

(A) a licensed pharmacy shall generally adhere to the documentation and standard operating procedures listed in USP <800> Section 17, except those listed in (vii)(B);

(B) a licensed pharmacy need not adhere to:

(I) environmental monitoring including wipe sampling; and

(II) medical surveillance; and

(viii) 18. MEDICAL SURVEILLANCE.

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

[~~In accordance with~~]Under Subsection 58-17b-601(1), this section establishes the operating standards for pharmacies that engage in central prescription processing as defined in Subsection 58-17b-102(9).

(1) Centralized prescription processing services may be performed if the parties have:

(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~~]the contract; and

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

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

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

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

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

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

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

(3) (a) "Non drug or device handling central prescription processing pharmacies,"[~~,~~] as defined in Subsection R156-17b-102(43), shall be licensed as Class E pharmacies.

(b) All other central prescription processing pharmacies shall be licensed in the appropriate pharmacy license classification.

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

(1) [~~In accordance with~~]Under Subsections 58-17b-102(58), 58-17b-601(1), 58-17b-612(1)(b), and 58-1-301(3), the operating standards for a remote dispensing pharmacy are established in this section.

(2) A remote dispensing pharmacy shall:

(a) be a Class A or Class B pharmacy;

(b) have a Class A or Class B pharmacy serve as its supervising pharmacy to oversee its operations; and

(c) be located in an area of need as defined in Subsection R156-17b-102(4).

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

(4) (a) The supervising pharmacy's PIC shall serve as the remote dispensing pharmacy's RDPIC[~~, who~~]and is responsible for any remote dispensing pharmacy operations.

(b) An RDPIC may not serve as the RDPIC for more than one remote dispensing pharmacy, unless approved by the Division in collaboration with the Board.

(5) (a) At any time that a remote dispensing pharmacy is open and available to serve patients, its pharmacy technicians shall be physically or electronically supervised by a pharmacist from the supervising pharmacy, under Subsection 58-17b-102(71).

(b) [~~In accordance with~~]Under Subsections 58-17b-612(1)(b) and (d), a pharmacist may oversee the operation of up to two remote dispensing pharmacies simultaneously.

(c) Unless a pharmacist is physically present, a remote dispensing pharmacy shall be staffed by no more than two licensed pharmacy technicians.

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

(e)[~~(i) Adequate supervision by a~~]A supervising pharmacist of a remote dispensing pharmacy:

(i) shall [~~include~~]maintain[~~ing~~] uninterrupted visual supervision and auditory communication with the site;[~~, and~~]

(ii) shall have full supervisory control of the automated system, if applicable[~~.~~]; and

(iii) [~~A supervising pharmacist~~]may not delegate supervision to any other [~~person~~]individual.

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

(a) provides comprehensive views of the entire site;

(b) facilitates adequate pharmacist supervision;

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

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

(e) is secure and HIPAA compliant as defined in Subsection R156-17b-102(67).

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

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

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

(b)[(i)] The plan shall:

(i) address the timely arrival of necessary personnel at the remote dispensing pharmacy[of necessary personnel,]; and

(ii) the delivery of necessary supplies to the remote dispensing pharmacy[~~of necessary supplies,~~] within a reasonable period following the identification of an emergency need.

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

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

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

(9) (a)[~~(i)~~] The remote dispensing pharmacy's security system shall [~~track~~]maintain a record of entries into the remote dispensing pharmacy to be periodically reviewed by the RDPIC.

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

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

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

(ii) the location of the supervising pharmacy; and

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

(10) Records, documentation, and recordings shall be subject to the following requirements:

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

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

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

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

([~~c~~]e)[~~(i)~~] The RDPIC shall oversee [~~documented~~]monthly inspections of the remote dispensing pharmacy[.] and [~~(ii) D~~]documentation of the inspections shall be kept for five years[,] and shall include:

([~~A~~]i) maintenance and reconciliation of any controlled substance;

([~~B~~]ii) a perpetual inventory of Schedule II controlled substances;

([~~C~~]iii) temperature logs of the refrigerator and freezer that hold medications; and

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

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

[~~In accordance with~~]Under Subsections 58-17b-102(47) and 58-17b-601(1), the operating standards for a Class C pharmacy[~~ies~~] designated as a pharmaceutical wholesaler[~~/~~] or distributor, [~~and~~]or as a pharmaceutical manufacturer [~~licensees~~] include[~~s~~] the following:

(1) Each pharmaceutical wholesaler or distributor or pharmaceutical manufacturer that distributes or manufactures drugs or medical devices in Utah shall be licensed by the Division.

(2) A separate license shall be obtained for each separate location engaged in the distribution or manufacturing of prescription drugs.

(3) A [~~B~~]business name[~~s cannot~~] may not be identical to a[~~the~~] name used by another unrelated wholesaler licensed to purchase drugs and devices in Utah.

([~~2~~]4) Manufacturers distributing only their own FDA-approved:

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

(b) devices or devices that are co-licensed products, including products packaged with devices, such as convenience kits, that are exempt from the definition of transaction in 21 USC sec. 360eee (24)(B)(xii-xvi) satisfy the requirement in Subsection (1) by registering their establishment with the FDA pursuant to 21 CFR Part 807.

([~~3~~]5) An applicant for licensure as a pharmaceutical wholesaler or distributor shall provide the following [~~minimum~~]information:

(a) [~~A~~]all trade or business names used by the licensee (including "doing business as" and "formerly known as");

(b) [~~N~~]name of the owner and operator of the license; and[~~ as follows:~~

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

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

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

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

~~(v) if a limited liability company~~

~~, the name of each member, social security number of each member, the name of each manager, the name of the limited liability company and federal employer identification number, and the name of the state where the limited liability company was organized; and]~~

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

([~~4~~]6) The licensed facility need not be under the supervision of a licensed pharmacist, but shall be under the supervision of a designated representative who meets the following criteria:

(a) is at least 21 years of age;

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

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

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

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

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

([~~5~~]7) The licensee shall provide the name, business address, and telephone number of [~~a~~]the individual serving [~~person to serve~~]as the designated representative for each facility of the pharmaceutical wholesaler that engages in the distribution of drugs or devices within 30 days of a change in designated representative.

([~~6~~]8) All pharmaceutical wholesalers and manufacturers shall [~~publicly~~]conspicuously display, or have readily available, all licenses and the most recent inspection report administered by the Division.

([~~7~~]9) All Class C pharmacies shall:

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

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

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

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

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

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

([~~8~~]10) Each facility used for wholesale drug distribution or manufacturing of prescription drugs shall:

(a) be secure from unauthorized entry;

(b) limit access from the outside [~~to a minimum in conformance with~~]following local building codes[~~,~~]and life and safety codes;[~~ and~~]

(c) control access to [~~persons~~]individuals to ensure unauthorized entry is not made;

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

([~~d~~]e) be well-lit [~~lighted~~]on the outside perimeter;

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

([~~f~~]g) be equipped with security measures, systems, and procedures necessary to provide reasonable security against:

(i) theft and diversion of prescription drugs; and[~~or~~]

(ii) alteration or tampering with computers and records pertaining to prescription drugs or prescription drug precursors.

([~~9~~]11) Each facility shall [~~provide the storage of~~]store prescription drugs, prescription drug precursors, and prescription drug devices [~~in accordance with~~]according to the following:

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

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

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

([~~10~~]12) Each [~~person~~]individual [~~who is~~]engaged in pharmaceutical wholesale distribution of prescription drugs for human use that leave, or have ever left, the normal distribution channel shall, before each pharmaceutical wholesale distribution of such drug, provide a pedigree to the person who receives such drug. [-]A retail pharmacy or pharmacy warehouse shall comply with the requirements of this section only if the pharmacy engages in pharmaceutical wholesale distribution of prescription drugs. The pedigree shall:

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

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

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

(iii) transaction dates;

(iv) name of the prescription drug;
(v) dosage form and strength of the prescription drug;
(vi) size of the container;
(vii) number of containers;
(viii) lot number of the prescription drug;
(ix) name of the manufacturer of the finished dose form; and
(x) National Drug Code (NDC) number.

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

([~~11~~]13) Each facility shall comply with the following requirements:

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

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

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

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

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

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

(ii) returns of expired, damaged, recalled, or otherwise non-saleable prescription drugs shall be distributed by the receiving pharmaceutical

wholesale distributor only to the original manufacturer or a third party returns processor that is licensed as a pharmaceutical wholesale distributor under this chapter;

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

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

([~~12~~]14) A manufacturer or pharmaceutical wholesaler shall furnish prescription drugs only to a person licensed by the Division or to another appropriate state licensing authority to possess, dispense, or administer such drugs for use by a patient.

([~~13~~]15) Prescription drugs furnished by a manufacturer or pharmaceutical wholesaler shall be delivered only to the business address of a person described in Subsections R156-17b-102(20)(c) and R156-17b-615, or to the premises listed on the license, or to an authorized person or agent of the licensee at the premises of the manufacturer or pharmaceutical wholesaler if the identity and authority of the authorized agent is properly established.

([~~14~~]16) Each facility shall establish and maintain records of all transactions regarding the receipt and distribution or other disposition of prescription drugs and prescription drug precursors and shall make inventories of prescription drugs and prescription drug precursors and required records available for inspection by authorized representatives of the federal, state, and local law enforcement agencies [~~in accordance with~~]according to the following:

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

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

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

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

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

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

(g) (i) records that are maintained on site or immediately retrievable from computer or other electronic means shall be made readily available for authorized inspection during the retention period; or

(ii) if records are stored at another location, they shall be made available within two working days after request by an authorized law enforcement authority during the two-[-]year period of retention.

([~~15~~]17) Each facility shall establish, maintain, and adhere to written policies and procedures that shall be followed for the receipt, security, storage, inventory, manufacturing, distribution, or other disposal of prescription drugs or prescription drug precursors, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. [~~In addition, t~~]The policies shall include the following:

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

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

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

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

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

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

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

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

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

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

([~~16~~]18) Each facility shall establish, maintain, and make available for inspection by authorized federal, state, and local law enforcement authorities, lists of all officers, directors, managers, and other [~~persons~~]individuals in charge, [~~which lists shall~~]including[~~e~~] a description of their duties and a summary of their background and qualifications.

(17) Each facility shall comply with laws including:

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

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

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

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

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

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

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

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

(i) are under the same ownership;

(ii) have processes and systems for separating and securing all aspects of the operation; and

(iii) have traceability with a clear audit trail that distinguishes a pharmacy's purchases and distributions.

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

(1) [~~In accordance with~~]Under Subsections 58-1-301(3) and 58-17b-306(2), an application for licensure as a Class D pharmacy shall include:

(a) a pharmacy care protocol that includes the operating standards established in Subsections R156-17b-610(1) and (8) and R156-17b-612(1) through (4);

(b) a copy of the pharmacist's license for the PIC; and

(c) a copy of the most recent state inspection or NABP inspection completed as part of the NABP Verified Pharmacy Program (VPP) showing the status of compliance with the laws and regulations for the physical facility, records, and operations.

(2) An out of state mail service pharmacy that compounds shall follow the USP-NF Chapter 795 Compounding of non-sterile preparations and Chapter 797 Compounding of sterile preparations.

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

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

([~~a~~]1) the identity of the supervisor or director;

([~~b~~]2) a detailed plan of care;

([~~c~~]3) the identity of the drugs to be purchased, stored, used, or accounted for; and

([~~d~~]4) the identity of any licensed healthcare provider associated with the operation.

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

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

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

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

(2) provide adequate lighting, ventilation, sanitation, space, equipment, and security conditions;

(3) maintain a list of drugs that will be purchased, stored, used, and accounted for;

(4) maintain a list of licensed health care providers associated with the operation of the business;

(5) possess prescription drugs for the purpose of analysis; and

(6) take measures to prevent the theft or loss of controlled substances.

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

(1) [~~In accordance with~~]Under Section 58-17b-302 and Subsection 58-17b-601(1), an animal control or animal narcotic detection training facility shall:

(a) maintain for immediate retrieval a perpetual inventory of all drugs including controlled substances that are purchased, stored, processed, and administered;

(b) maintain for immediate retrieval a current list of authorized employees and their training [~~with regards to the~~]on handling and using[~~e of~~] legend drugs and[~~/or~~] controlled substances [~~in relation to~~]for euthanasia, immobilization, or narcotic detection training of animals;

(c) maintain[~~,~~] for immediate retrieval documentation of all required materials [~~pertaining to~~]for legitimate animal scientific drug research, guidance policy, and other relevant documentation from the agency's Institutional Review Board, if applicable;

(d) maintain stocks of legend drugs and controlled substances to the smallest quantity needed for efficient operation to conduct animal euthanasia, immobilization, or narcotic detection training purposes;

(e) maintain all legend drugs and controlled substances in an area within a building having perimeter security that limits access during working hours, provides adequate security after working hours, and has the following security controls:

(i) a permanently secured safe or steel cabinet substantially constructed with self-closing and self-locking doors employing either multiple position combination or key lock type locking mechanisms; and

(ii) requisite key control, combination limitations, and change procedures;

(f) have only one [~~a responsible party who is the~~ only ~~person~~]individual authorized to purchase and reconcile legend drugs and controlled substances and is responsible for the inventory of the animal control or animal narcotic detection training facility pharmacy;

(g) ensure that only defined and approved individuals pursuant to the written facility protocol have access to legend drugs and controlled substances; and

(h) develop and maintain written policies and procedures for immediate retrieval that include the following:

(i) the type of activity conducted with [~~regards to~~]legend drugs and[~~/or~~] controlled substances;

(ii) how medications are purchased, inventoried, prepared, and used [~~in relation to~~]for euthanasia, immobilization, or narcotic detection training of animals;

(iii) the type, form, and quantity of legend drugs and[~~/or~~] controlled substances handled;

(iv) the type of safe, or equally secure [~~enclosures or other~~]storage system, used for the storage and retrieval of legend drugs and[~~/or~~] controlled substances;

(v) security measures in place to protect against theft or loss of legend drugs and controlled substances;

(vi) adequate supervision of employees having access to manufacturing and storage areas;

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

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

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

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

(1) [~~In accordance with~~]Under Section 58-17b-302 and Subsection 58-17b-601(1), a durable medical equipment facility shall:

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

(b) provide adequate lighting, ventilation, sanitation, space, equipment, and security conditions;

(c) be equipped [~~to permit~~]for the orderly storage of durable medical equipment in:

(i) a manner [~~to~~]permitting clear identification, separation, and easy retrieval of products; and

(ii) an environment necessary to maintain the integrity of the product inventory;

(d) be equipped [~~to permit~~]for practice within the standards and ethics of the profession as dictated by the [~~usual and ordinary~~]scope of practice [~~to be~~]conducted within the[~~at~~] facility;

(e) maintain prescription forms and records for a period of five years;

(f) be locked and enclosed [~~in such as way as~~]to bar entry by the public or any non-personnel when the facility is closed; and

(g) conspicuously display[~~post~~] the license [~~of~~]for the facility[~~ in full view of the public~~].

(2) A licensed practitioner who administers durable medical equipment to a patient or animal is not engaging in the practice of pharmacy[~~,~~] and does not require a license as a Class E pharmacy.

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

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

(2) Under Subsections 58-37-[~~6(2)(b)~~]105(2)(b) and (3)(a)(i), [~~persons~~]individuals licensed to conduct research in Utah with controlled substances in Schedules I-V may possess, manufacture, produce, distribute, prescribe, dispense, administer, conduct research with, or perform laboratory analysis upon those substances to the extent authorized by their license.

(3) Under Subsection 58-37-[~~6(2)~~]105, the following [~~persons~~]individuals are not required to obtain a license and may lawfully possess controlled substances in Schedules II-V:

(a) an agent or employee acting in the usual course of the [~~person's~~]individual's business or employment[~~,~~]; and

(b) an ultimate user[~~, or a person~~] who possesses a controlled substance pursuant to a lawful order of a practitioner.

(4) A separate license is required at each principal place of business or professional practice where the applicant manufactures, produces, distributes, dispenses, conducts research with, or performs laboratory analysis upon controlled substances.

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

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

([~~a~~]1) develop a standard operating policy and procedures manual;

([~~b~~]2) conduct training and maintain evidence of employee training programs and completion certificates;

([~~c~~]3) maintain documentation and records of all transactions, including[~~ to include~~]:

([~~i~~]a) batch production records;

([~~ii~~]b) certificates of analysis; and

([~~iii~~]c) dates of calibration of gauges;
([~~d~~]4) provide adequate space for orderly placement of equipment and finished product;
([~~e~~]5) maintain gas tanks securely;
([~~f~~]6) designate return and quarantine areas for separation of products;
([~~g~~]7) label all products;
([~~h~~]8) fill cylinders without using adapters; and
([~~i~~]9) comply with all FDA standards and requirements.

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

Under Section 58-17b-601(1), a third party logistics provider:

(1) [~~A third party logistics provider~~]shall comply with DSCSA standards; and[~~.~~]

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

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

(1) Under Section 58-17b-614, a[~~A~~] licensed pharmacy or pharmaceutical facility shall:

(a) apply for a new license and receive approval from the Division at least ten business days before a Qualifying Ownership Change; and

(b) upon approval of the Qualifying Ownership Change and issuance of a new license, the pharmacy or pharmaceutical facility shall surrender its original license to the Division.

(2) (a) Under Subsection 58-17b-614(2), a request by a pharmacy or pharmaceutical facility to change its name when the change is not due to, or in anticipation of, a Qualifying Ownership Change shall be [~~received by~~]submitted to the Division no later than ten business days before the proposed effective date of the name change.

(b) [~~This~~]Subsection (2) applies to any change in name, including:

(i) changes to the pharmacy or pharmaceutical facility's registered corporate name; and

(ii) addition or removal of a doing-business-as (DBA) name.

(c) If the requested name change requires [~~a~~]filing with the Division of Corporations and Commercial Code, or equivalent state agency in the jurisdiction where the name change will be effectuated, the applicant shall submit with the request proof of such filing with an effective date of no fewer than ten days following the date of the request.

(3) (a) Under Subsection 58-17b-306(3)(b), a request by a pharmacy or pharmaceutical facility to update its address for reasons not due to, or in anticipation of, a Qualifying Ownership Change shall be [~~received by~~]submitted to the Division no later than 90 business days before the proposed effective date of the address change.

(b) If the pharmacy or pharmaceutical facility's new address is located within the state, the request shall include a request for inspection of the new facility.

(c) If the pharmacy or pharmaceutical facility's new address is located outside the state:

(i) the request shall include a copy of a request for inspection filed with the government agency with jurisdiction over the inspection at the new address; and

(ii) upon receipt of the inspection report from the government agency under Subsection (3)(b)(i), the pharmacy or pharmaceutical facility shall submit to the Division within ten days:

(A) a copy of the inspection report; and

(B) an affidavit signed by the pharmacy manager that the inspection report is an accurate copy.

(4) If a pharmacy or pharmaceutical facility requesting a change in name or address does not comply with the requirements of Subsection (3) or Subsection (4), the pharmacy or pharmaceutical facility shall:

(a) apply for a new license; and

(b) upon approval of the application by the Division and the issuance of a new license, surrender the original license to the Division.

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

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

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

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

~~(b) manufacturer's name and model;~~

~~(c) description of how the device is used;~~

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

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

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

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

~~(4) Automated pharmacy systems shall have:~~

~~(a) adequate security systems and procedures to:~~

~~(i) prevent unauthorized access;~~

~~(ii) comply with federal and state regulations; and~~
~~(iii) prevent the illegal use or disclosure of protected health information;~~
~~(b) written policies and procedures in place prior to installation to ensure safety, accuracy, security, training of personnel, and patient confidentiality and to define access and limits to access to equipment and medications.~~
~~(5) Records and electronic data kept by automated pharmacy systems shall meet the following requirements:~~
~~(a) all events involving the contents of the automated pharmacy system must be recorded electronically;~~
~~(b) records must be maintained by the pharmacy for a period of five years and must be readily available to the Division. Such records shall include:~~
~~(i) identity of system accessed;~~
~~(ii) identify of the individual accessing the system;~~
~~(iii) type of transaction;~~
~~(iv) name, strength, dosage form and quantity of the drug accessed;~~
~~(v) name of the patient for whom the drug was ordered; and~~
~~(vi) such additional information as the PIC may deem necessary.~~
~~(6) Access to and limits on access to the automated pharmacy system must be defined by policy and procedures and must comply with state and federal regulations.~~
~~(7) The PIC or pharmacist designee shall have the responsibility to ensure that:~~
~~(a) user access to the system is assigned, discontinued or changed according to employment status and credentials;~~
~~(b) access to the medications comply with state and federal regulations; and~~
~~(c) the automated pharmacy system is filled and stocked accurately and in accordance with established written policies and procedures.~~
~~(8) The filling and stocking of all medications in the automated pharmacy system shall be accomplished by qualified licensed healthcare personnel under the supervision of a licensed pharmacist.~~
~~(9) A record of medications filled and stocked into an automated pharmacy system shall be maintained for a period of five years and shall include the identification of the persons filling, stocking and checking for accuracy.~~
~~(10) All containers of medications stored in the automated pharmacy system shall be packaged and labeled in accordance with federal and state laws and regulations.~~
~~(11) All aspects of handling controlled substances shall meet the requirements of all state and federal laws and regulations.~~
~~(12) The automated pharmacy system shall provide a mechanism for securing and accounting for medications removed from and subsequently returned to the automated pharmacy system, all in accordance with existing state and federal law. Written policies and procedures shall address situations in which medications removed from the system remain unused and must be secured and accounted for.~~
~~(13) The automated pharmacy system shall provide a mechanism for securing and accounting for wasted medications or discarded medications in accordance with existing state and federal law. Written policies and procedures shall address situations in which medications removed from the system are wasted or discarded and must be secured.~~]

Under Section 58-17b-621, an automated pharmacy system shall comply with the following:

(1) The pharmacy responsible for the automated pharmacy system shall maintain the following documentation, for review upon Division request:

(a) types of automated pharmacy system equipment, content, and location, including:

(i) name and address of the pharmacy or licensed health care facility using the automated pharmacy system;

(ii) manufacturer's name and model;

(iii) serial numbers; and

(iv) description of how the automated pharmacy system is used; and

(b) written policies and procedures for quality assurance and appropriate use of the automated pharmacy system including:

(i) operation;

(ii) safety;

(iii) security;

(iv) accuracy;

(v) automated pharmacy system malfunction;

(vi) patient confidentiality;

(vii) access to the equipment and medications;

(viii) training of personnel; and

(ix) procedures for securing and accounting for medications that are removed from the system and not used, including situations when the unused medications are wasted and discarded.

(2) The pharmacy responsible for the automated pharmacy system and the documentation in Subsection (1) shall:

(a) have the documentation in Subsection (1) in place prior to installation of the automated pharmacy system;

(b) maintain the documentation at the site of the pharmacy, and if the automated pharmacy system is not in the facility where the pharmacy is located, at the site of the automated pharmacy system; and

(c) provide the documentation to the Division for review upon request.

(3) Filling and stocking medications in the automated pharmacy system shall be done by qualified licensed health care personnel under the supervision of a licensed pharmacist.

(4) A pharmacist shall review each prescription or medication order before dispensing, or removing from an automated pharmacy system, unless:

(a) a licensed independent practitioner controls the ordering, preparation, and administration of the medication; or

(b) the pharmacist review would result in a delay that would harm the patient, including situations in which the patient experiences a sudden change in clinical status.

(5) An automated pharmacy system shall have:

(a) adequate security systems and procedures to prevent:

(i) unauthorized access; and

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

(b) a mechanism for securing and accounting for medications removed from and subsequently returned to the automated pharmacy system; and

(c) a mechanism for securing and accounting for wasted medications or discarded medications.

(6) Records including electronic data kept by an automated pharmacy system shall meet the following requirements:

(a) each event involving the contents of the automated pharmacy system shall be recorded electronically;

(b) the pharmacy shall maintain records for five years, and keep them readily available to the Division upon request; and

(c) each record shall include:

(i) identity of the system accessed;

(ii) identity of the individual accessing the system;

(iii) identity of each individual filling, stocking, and checking for accuracy;

(iv) type of transaction;

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

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

(vii) additional information that the PIC may determine necessary.

(7) The PIC or pharmacist designee shall ensure that:

(a) user access to the automated pharmacy system is assigned, discontinued, or changed according to employment status and credentials; and

(b) the automated pharmacy system is filled and stocked accurately in accordance with policies and procedures.

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

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

(1) Prior to [~~engaging in the administration of~~]administering a long-acting injectable drug pursuant to Section 58-17b-625, a pharmacist shall successfully complete:

(a) current Basic Life Support (BLS) certification; and

(b) a training program for administering long-acting injectables intramuscularly that is provided by an ACPE-accredited provider.

(2) An individual who [~~engages in the administration of~~]administers long-acting injectable drugs intramuscularly shall maintain documentation that they obtained their required training.

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

(1) [~~In accordance with~~]Under Subsection R156-17b-102(21)(c), a formal or on-the-job dispensing training program completed by a DMP designee is one that covers the following topics to the extent that the topics are relevant and current to the DMP practice where the DMP designee is employed:

(a) role of the DMP designee;

(b) laws affecting prescription drug dispensing;

(c) pharmacology, including the identification of drugs by trade and generic names, and therapeutic classifications;

(d) pharmaceutical terminology, abbreviations, and symbols;
(e) pharmaceutical calculations;
(f) drug packaging and labeling;
(g) computer applications in the pharmacy;
(h) sterile and non-sterile compounding;
(i) medication errors and safety;
(j) prescription and order entry and fill process;
(k) pharmacy inventory management; and
(l) pharmacy billing and reimbursement.

(2) Documentation demonstrating successful completion of a formal or on-the-job dispensing training program shall include the following information:
(a) name of individual trained;
(b) name of individual or entity that provided training;
(c) list of topics covered during the training program; and
(d) training completion date.

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

The drugs that may be dispensed by a DMP in accordance with Subsection 58-17b-802(1) and Section 58-17b-803 are limited to:
(1) the following cosmetic drugs:
(a) Latisse or generic equivalent; and
(b) the injectable weight loss drug human chorionic gonadotropin; and
(2) the following legend, non-controlled drugs:
(a) hormonal based contraception unless using [~~except~~]exempt injectable or implantable methods;
(b) hydroquinone up to 4%; and
(c) tretinoin up to 0.1%.

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

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

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

(1) [~~In accordance with~~]Under Subsections [~~26-55-105~~]26B-4-510(2)(c) and (d), the pharmacist-in-charge or a responsible corporate officer of each pharmacy licensee that dispenses an opiate antagonist pursuant to a valid standing prescription drug order issued by a physician, shall:

(a) affirm that the pharmacy licensee has complied with the protocol for dispensing an opiate antagonist as set forth in Section [~~26-55-105~~]26B-4-510;[,] and[~~shall~~]

(b) annually report[~~, on an annual basis,~~] to the [~~d~~]Division and to the physician who issued the opiate antagonist standing drug order, the following information:

([~~a~~]i) the total number of single doses of opiate antagonists dispensed during the reporting period; and

([~~b~~]ii) the name of each opiate antagonist dispensed[~~, along with~~]; and

(iii) the total number of single doses of [~~that particular~~]each named opiate antagonist.

(2) Corporations or organizations with multiple component pharmacy licenses may submit one cumulative report for all [~~its~~]component pharmacy licensees so long as the report [~~. However, that report must~~]contains the information described [~~above~~]in Subsection (1) for each of the component pharmacy licensees.

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

(4) The annual affirmation and report [~~described above is due~~]shall be submitted to the [~~d~~]Division and to the physician who issued the standing drug order no later than 15 days following December 31 of each calendar year.

(5) [~~In accordance with~~]Under Subsection [~~26-55-105~~]26B-4-510(2)(d), a pharmacy licensee who dispenses an opiate antagonist pursuant to a valid standing prescription order issued by a physician, shall maintain, subject to audit, the following information:

(a) the name of the individual to whom the opiate antagonist is dispensed;

(b) the name of the opiate antagonist dispensed;

(c) the quantity of the opiate antagonist dispensed;

(d) the strength of the opiate antagonist dispensed;

(e) the dosage quantity of the opiate antagonist dispensed;

(f) the full name of the drug outlet which dispensed the opiate antagonist;

(g) the date the opiate antagonist was dispensed; and

(h) the name of the physician issuing the standing order to dispense the opiate antagonist.

(6) The [~~d~~]Division approves the protocol for the issuance of a standing prescription drug order for opiate antagonists under Subsection 26B-4-510(3) and Sections R156-17b-625, R156-67-604, and R156-68-604[~~, which is set forth in Subsection 26-55-105(2)(a) through (d) along with the requirements set forth in the foregoing provisions, and the reporting requirements set forth in Sections R156-67-604 and R156-68-604~~].

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

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

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

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

(1) Under Subsection 58-17b-601(1) and Sections 58-17b-602, 58-17b-609, and 58-17b-627, a pharmacist from a Class A or Class B pharmacy may prescribe a prescription drug or device as follows:

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

(i) current health status;

(ii) past medical history;

(iii) allergies;

(iv) medication sensitivities;

(v) rationale for care;

(vi) current medication; and

(vii) if the pharmacist should refer the patient to an appropriate health care provider or otherwise encourage the patient to seek further medical care.

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

(i) the Centers for Disease Control and Prevention;

(ii) nationally accepted guidelines; and

(iii) the Department of Health and Human Services and the Division in collaboration with the Board, in the guidance documents [~~incorporated by reference~~]in Subsection (2)[~~(a)~~].

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

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

(i) monitoring parameters for efficacy and safety;

(ii) adverse reactions; and

(iii) further medical care.

([~~e~~]d) [~~(i) (A)~~]The pharmacist shall notify the patient's primary care or other health care provider about the prescription according to the following requirements:

(i) provide notification within five business days of the prescribing;[~~.~~]

([~~B~~]ii) [~~The prescription notification may be~~]convey[~~ed~~] the prescription notification in writing, by electronic transmission, or by telephone;[~~.~~]

([~~C~~]iii) [~~I~~]if the patient does not have a primary care or other health care provider, the pharmacist shall provide the prescription notification to the patient;[~~.~~]

([~~D~~]iv) [~~T~~]the pharmacy shall maintain the prescription notification in the patient record for at least five years from the date of notification, in an immediately retrievable written or electronic format; and[~~.~~]

([~~ii~~]v) [~~E~~]each prescription notification shall include the following:

(A) prescribing pharmacist;

(B) pharmacy name;

(C) pharmacy phone number;

(D) patient;

(E) patient date of birth;

(F) drug or device;
(G) if dispensed, dispensed quantity;
(H) directions for use;
(I) refill; and
(J) identity of the patient's primary care or other health care provider, if any.

(2)[~~(a)~~] A pharmacist may prescribe drugs or devices under Subsection 58-17b-627(3)(a) as established in the following guidance documents posted on the Division's website at dopl.utah.gov/pharm:

([~~i~~]a) Utah Guidance for Pre-Exposure and Post-Exposure Prophylaxis of HIV[~~, adopted September 28, 2021~~];

([~~ii~~]b) Utah Guidance for Self-Administered Hormonal Contraceptives[~~, adopted September 28, 2021~~];

([~~iii~~]c) Utah Guidance for Tobacco Cessation Products[~~, adopted September 28, 2021; and~~];

([~~iv~~]d) Utah Guidance for Naloxone[~~, adopted September 28, 2021.~~];

(e) Utah Guidance for Fluoride;

(f) Utah Guidance for Vaccine Prescription and Administration; and

(g) Utah Guidance for Epinephrine.

[~~(b) The Division incorporates by reference the guidance documents in Subsection (2)(a).~~]

(3) (a) The Department of Health and Human Services may submit to the Division a written proposal that includes:

(i) under Subsection 58-17b-627(3)(a), designated public health concerns that the Department of Health and Human Services has determined can be addressed through pharmacist prescribing of drugs or devices; and

(ii) recommendations for updates to the guidance documents in Subsection (2); and

(b) after receipt of the [~~designation~~]proposal, the Division:

(i) shall contact the Department of Health and Human Services to review [~~its~~]the proposal;

(ii) may review Division rules, and the guidance documents in Subsection (2) in response to the proposal; and

(iii) may [~~review~~]amend [~~the~~]Division rules[~~ made by the Division, including~~] and the guidance documents in Subsection (2)[~~,~~] in accordance with Subsections 58-17b-627(3) and (4).

[~~(4) The Division shall review the guidance documents in Subsection (2) biennially, in collaboration with:~~

~~(a) the Board;~~

~~(b) the individuals identified in Subsection 58-17b-627(4); and~~

~~(c) other persons as determined by the Division.~~]

R156-17b-628. Operating Standards - Prescriptions Issued Within the Public Health System.

[~~(1) -~~]Under Subsections 58-17b-620(7) and (8), a nurse employed by a health department and licensed under Title 58, Chapter 31b, Nurse Practice Act, may dispense a drug to treat a sexually transmitted infection as established in the Utah Guidance for Dispensing by Health Department Nurse of STI Drug[~~, adopted August 23, 2022,~~] posted on the Division's website at dopl.utah.gov/pharm.

[~~(2) The Division incorporates by reference the guidance document in Subsection (1).~~]

R156-17b-1005. Operating Standards -- Standing Prescription Orders for Emergency Medications Use as School Stock.

(1) [~~In accordance with~~]Under Subsection 58-17b-601(1), the Division approves [~~all~~]standing orders required by statute and issued by the Utah Department of Health and Human Services relating to dispensing of emergency use medication to be held as school stock.

(2) Authorized standing orders referenced in Subsection [~~1005~~](1) can be found on the Division's website at https://[~~dopl~~]commerce.utah.gov/dopl/pharmacy/resources/.

KEY: pharmacists, licensing, pharmacies
Date of Last Change: August 8, 2025
Notice of Continuation: August 5, 2024
Authorizing, and Implemented or Interpreted Law: 63G-3-201; 58-17b-101; 58-17b-601(1); 58-37-1; 58-1-106(1)(a); 58-1-202(1)(a)