

(3) Remaining earnings of individual accounts within the trust shall, except as provided in Subsection 58-9-704(3), remain in each individual account within the trust to pay by account, the costs of providing the goods and services required under respective preneed funeral arrangement contracts.

**R156-9-[615]614. Maximum Life Insurance Proceeds Payable to Funeral Service Establishment.**

(1) Preneed life insurance proceeds payable to a funeral service provider shall not exceed the funeral service establishment's insurable interest in the recipient of goods and services which, by definition, shall not exceed the funeral service establishment's current retail price for the goods and services provided, as determined by the funeral service establishment's price list in effect at the recipient of goods and service's death.

(2) Excess preneed life insurance proceeds not paid to the funeral service establishment shall be returned to the owner of the life insurance policy or his heirs and beneficiaries unless otherwise designated by the owner or his heirs and beneficiaries.

**R156-9-[616]615. Reporting Requirements.**

(1) In accordance with Sections 58-9-504 and 58-9-706, each funeral service establishment shall maintain an annual report at the establishment which shall be subject to Division audit at anytime. The annual report shall be maintained in a format set forth by the Division and shall include:

(a) a statement of compliance certifying:

(i) that all payments received from the sale of contracts have been:

(A) placed in the funeral service establishment's trust account in accordance with Section 58-9-702 and administered in accordance with Sections 58-9-703 through 58-9-705 and this rule; or

(B) submitted to the insurance company whose insurance or annuity policy funds the contract;

(ii) that complete and accurate information concerning the preneed funeral arrangements by the funeral service establishment or the funeral service establishment's sales agent was furnished or made available to the independent certified public accountant who prepared the report of agreed upon procedures; and

(iii) that the annual report is complete and accurate;

(b) at least one of the following reports which reconciles balances in all trust accounts and insurance policies to those in the annual report:

(i) a report from a bank trust department;

(ii) a report from a licensed insurance company; or

(iii) an accounting report on forms available from the Division, completed by an independent certified public accountant (CPA) licensed pursuant to Title 58, Chapter 26a, which report indicates the procedures used and agreed upon by the CPA and the funeral service establishment.

(c) an exhibit listing preneed contracts sold prior to April 29, 1991, funded by money, 75% of which is required to be maintained in the name of the contract buyer in the funeral service establishment's trust account as provided in Section 58-9-703, which shall include at a minimum: the contract number, date, amount, the recipient of goods and services and buyer if different, and balance due; the individual trust account number and amount trusted; and the trust earnings, earnings used, and trust balance;

(d) an exhibit listing preneed contracts sold after April 28, 1991, funded by money, 100% of which is required to be maintained in the name of the contract buyer in the funeral service establishment's trust account as provided in Section 58-9-703, which shall include at a minimum the information required under subsection (c);

(e) an exhibit listing preneed contracts funded by money placed in trust which were serviced, revoked, rescinded, or amended since the last reporting period, which shall include at a minimum: the contract number, date, amount, the recipient of goods and services and buyer if different; the individual trust account number and trust balance at the recipient of goods and service's death; the date the contract was closed; and an explanation regarding any preneed contract closed but not serviced;

(f) an exhibit listing preneed contracts sold after April 28, 1991, funded in whole or in part by insurance, which shall include at a minimum: the contract number, date, amount, recipient of goods and services and buyer if different; the insurance company; the policy number, policy holder, and face amount; and

(g) an exhibit listing preneed contracts funded by insurance which were serviced, revoked, rescinded, or otherwise amended since the last reporting period, which shall include at a minimum: the contract number, date, amount, the recipient of goods and services, and buyer if different; the insurance company; the policy number and policy holder; the policy proceeds; the date the contract was closed; and an explanation regarding any preneed contract closed but not serviced.

**R156-9-[617]616. Maximum Revocation Fee.**

If a buyer revokes or defaults under a guaranteed preneed funeral arrangement contract, the funeral service establishment may retain a revocation fee from the trust corpus, not to exceed 25% of the amount received from the sale of the contract and trust earnings thereupon, provided the revocation fee is clearly identified in the contract.

**R156-9-[618]617. Goods and Services Not Provided - Refund.**

If goods or services selected in the preneed contract are not provided at the time of need, the amount paid for those goods and services and any unexpended earnings thereupon will be distributed to the preneed contract buyer or the buyer's representative or in their absence, the buyer's heirs and beneficiaries.

**KEY: funeral industries, licensing, funeral service directors, preneed funeral arrangements**

**Date of Enactment or Last Substantive Amendment:**  
~~September 10, 2018~~ 2019

**Notice of Continuation:** April 26, 2016

**Authorizing, and Implemented or Interpreted Law:** 58-1-106(1) (a); 58-1-202(1)(a); 58-9-504

Commerce, Occupational and  
Professional Licensing  
**R156-17b**  
Pharmacy Practice Act Rule

**NOTICE OF PROPOSED RULE  
(Amendment)**

DAR FILE NO.: 44108  
FILED: 09/30/2019

**RULE ANALYSIS**

**PURPOSE OF THE RULE OR REASON FOR THE CHANGE:** In accordance with S.B. 170, passed during the 2019 General Session, this rule filing establishes the scope of practice for pharmacy technicians in rule, and expands their scope to include administering immunizations and emergency medications pursuant to delegation by a pharmacist. Also, in accordance with S.B. 170 (2019), this filing clarifies the requirements and operating standards for the practice of telepharmacy through a remote dispensing pharmacy. This filing also proposes amendments recommended by the Division of Occupational and Professional Licensing (Division) in collaboration with the Pharmacy Licensing Board (Board), including creation of an Advisory Pharmacy Compounding Education Committee, and clarification of various requirements, including operating standards for a third party logistics provider, required licensee training and education, and required continuing education topics. Various updates and nonsubstantive formatting changes are also made throughout the rule.

**SUMMARY OF THE RULE OR CHANGE:** The proposed substantive amendments in this filing are as follows: In Section R156-17b-102, adds definitions for the terms "Area of need", "Mail service retail pharmacy", "MPJE", "Remote Dispensing Pharmacist in Charge"/"RDPIC", "Remote dispensing pharmacy", "Retail Pharmacy", "Supervising pharmacy", and "Telepharmacy system". In Section R156-17b-106, clarifies the use of "shall" or "may" as used in this rule. Although these conventions are understood for Utah laws and rules, adding this special clarification to the pharmacy rule is important because there are other standards that apply in the pharmacy profession when using the terms shall and may. In Section R156-17b-203, creates an Advisory Pharmacy Compounding Education Committee (Committee). The Committee shall be composed of seven members, diversified between retail pharmacy, hospital pharmacy, and other pharmacy specialties deemed pertinent by the Division in collaboration with the Board. In Section R156-17b-302, clarifies that Class A pharmacies include retail pharmacies, mail service retail pharmacies, and remote dispensing pharmacies, and that a Class A pharmacy needs a PIC or a remote dispensing pharmacist in charge (RDPIC). In Section R156-17b-303a, clarifies that an applicant may prove current college admission by written verification from "a" dean of the college. In Section R156-17b-303c, clarifies that a pharmacist applicant will need to take the Utah MPJE exam. In Section R156-17b-304, clarifies that a temporary pharmacist will need to submit evidence of having secured employment in Utah conditioned upon issuance of the temporary license, and that the employment is under the direct, on-site supervision of a pharmacist with an active, non-temporary Utah license that includes a controlled substance license. In Section R156-17b-305, clarifies licensure by

endorsement requirements for a pharmacist. In Section R156-17b-309, updates the continuing education topics and requirements for pharmacists and pharmacy technicians, including requiring two CE hours in immunizations or vaccine-related topics for pharmacy technicians who engage in the administration of immunizations or vaccines. In Section R156-17b-402, replaces all administrative penalty subsections with a fine schedule. In Section R156-17b-502, formats certain provisions to fit with the new fine schedule, and adds to the definition of unprofessional conduct "failing to comply with the operating standards for a remote dispensing pharmacy as established in Section R156-17b-614g". In Section R156-17b-601, clarifies the scope of practice for pharmacy technicians and pharmacy technician trainees. In particular, this amendment will allow pharmacy technicians to administer vaccines and emergency medications pursuant to delegation by a pharmacist under the Vaccine Administration Protocol: Standing Order to Administer Immunizations and Emergency Medications adopted March 26, 2019, if the pharmacy technician completes certain required initial training and CE, and is under direct, on-site supervision by the delegating pharmacist. In Section R156-17b-610, clarifies that patient counseling may be provided through a telepharmacy system. In Section R156-17b-612, minor wording changes were made in this section regarding prescriptions operating standards. In Section R156-17b-614a, clarifies that a remote dispensing pharmacy may dispense a prescription drug or device to a patient if a pharmacist or DMP is physically present and immediately available in the facility, or supervising through a telepharmacy system. Section R156-17b-614g is new and establishes and clarifies the qualifications and operating standards for a remote dispensing pharmacy. In Section R156-17b-615, clarifies that a Class C pharmacy may be located in the same building as a separately licensed Class A, B, D, or E third-party logistics provider. Section R156-17b-617g is new and establishes operating standards for a third party logistics provider. In Section R156-17b-621, allows pharmacy interns and pharmacy technicians to administer immunizations and emergency medications pursuant to delegation by a pharmacist under the March 26, 2019, Vaccine Administration Protocol, and establishes and clarifies the required training for pharmacists, pharmacy interns, and pharmacy technicians who will be engaging in the administration of a prescription drug or device, or engaging in the administration of vaccines. In Section R156-17b-623, clarifies the drugs that may be dispensed by a dispensing medical practitioner in accordance with Subsection 58-17b-802(1) and Section 58-17b-803.

**STATUTORY OR CONSTITUTIONAL AUTHORIZATION FOR THIS RULE:** Section 58-17b-101 and Section 58-37-1 and Subsection 58-1-106(1)(a) and Subsection 58-1-202(1)(a) and Subsection 58-17b-601(1)

**MATERIALS INCORPORATED BY REFERENCE:**

- ◆ Removes Model Policy for the Use of Controlled Substances for the Treatment of Pain, published by Federation of State Medical Boards of the United States, Inc. (FSMB), May 2004

**ANTICIPATED COST OR SAVINGS TO:**

◆ **THE STATE BUDGET:** The Committee created in the new proposed Section R156-17b-203 will be required to meet at least once per calendar quarter, and as directed by the Board and Division. Pursuant to Section R156-1-205, the seven Committee members will serve on a volunteer basis and are not entitled to receive per diem, travel expenses, or other compensation from the state, but the Division is required to provide a Division employee to act as Committee secretary. With an estimated five 1-1/2 hour meetings per year, attended by one bureau manager at \$45 per hour and one Committee secretary at \$20 per hour, and anticipated additional work time of two hours per meeting for the Committee secretary at \$20 per hour, the Division estimates that it will experience a fiscal cost from this proposed amendment of approximately \$688 per fiscal year ongoing. The amendments to Sections R156-17b-601 and R156-17b-621 are based on the Utah Pharmacy Practice Act as amended by S.B. 170 (2019), which provides for the scope of practice for a Pharmacy Technician to be established by rule. The amendments expand the scope of practice in that they allow pharmacy interns and pharmacy technicians to engage in the administration of vaccines and emergency medications. The Division estimates that this may result in a potential increase of one additional complaint of unprofessional conduct each year, requiring one investigation consisting of approximately 20 hours. This may result in a cost to Division investigations of approximately \$500 per fiscal year ongoing. The remaining amendments are not expected to have any fiscal impact to state practices and procedures beyond that anticipated by the fiscal note for S.B. 170 (2019), available at: <https://le.utah.gov/~2019/bills/static/SB0170.html>.

Additionally, as described below in the analysis for small businesses and non-small businesses, the Division does not expect any state agencies that may be acting as employers to experience any measurable fiscal impacts. The proposed amendments relating to the practice of telepharmacy and remote dispensing pharmacies may result in fiscal and non-fiscal benefits to any state agencies that may use such services or act as businesses in this industry, but as described below in the analysis for small businesses and non-small businesses, an exact estimate of these benefits is not possible because the relevant data is unavailable. The proposed amendments to Section R156-17b-617g providing operating standards for third party logistics providers define practices currently in place by the Drug Supply Chain Security Act (2019). The Division estimates that this may result in a potential increase of one additional complaint of unprofessional conduct each year requiring one investigation consisting of approximately 20 hours. This may result in a cost to the Division investigations of approximately \$500 per fiscal year ongoing. None of the other proposed rules or amendments are expected to impact state government revenues or expenditures. They will not change existing state practices or procedures and merely update the rule to establish definitions, clarify standards, encompass current requirements and practices in the profession, and make formatting changes for clarity. No other measurable impact on state government revenues or expenditures is expected

beyond a minimal cost to the Division of approximately \$75 to disseminate the rule once the proposed amendments are made effective.

◆ **LOCAL GOVERNMENTS:** The amendments to Sections R156-17b-601 and R156-17b-621 that will allow pharmacy interns and pharmacy technicians to engage in the administration of vaccines and emergency medications are not expected to have any fiscal impact to local governments beyond that anticipated by the fiscal note for S.B. 170 (2019), and as described below in the analysis for small businesses and non-small businesses, the Division does not expect any local governments that may be acting as employers to experience any measurable fiscal impacts. The proposed amendments relating to the practice of telepharmacy and remote dispensing pharmacies may result in fiscal and non-fiscal benefits to local governments that may use such services or act as businesses in this industry, but as described below in the analysis for small businesses and non-small businesses, an exact estimate of these benefits is not possible because the relevant data is unavailable. None of the other proposed rules or amendments are expected to impact local governments' revenues or expenditures because they only update the rule to establish definitions, clarify standards, encompass current requirements and practices in the profession, and make formatting changes for clarity.

◆ **SMALL BUSINESSES:** The amendments to Sections R156-17b-601 and R156-17b-621 allowing pharmacy interns and pharmacy technicians to engage in the administration of vaccines and emergency medications are expected to create a fiscal benefit for the approximately 508 Class A retail pharmacies, 284 Class B pharmacies, and 1,188 Class C pharmacies licensed in Utah that are small businesses (NAICS 446110). The amended rule will allow these non-small businesses to offer more services and thereby increase their revenue. The precise fiscal benefit is inestimable because the data necessary to determine how many small business pharmacies will elect to hire pharmacy interns and pharmacy technicians to provide vaccination services is not available, and because any increase in revenue will vary depending on the characteristics of each small business and on the licensees that the business chooses to employ. The proposed amendments relating to the practice of telepharmacy and remote dispensing pharmacies may impact the approximately 508 Class A retail pharmacies and 284 Class B pharmacies licensed in Utah that are small businesses (NAICS 446110). These amendments are expected to decrease operating costs and increase revenues for Class A pharmacies or Class B pharmacies that choose to serve as supervising pharmacies or are designated as remote dispensing pharmacies, because these pharmacies will be able to provide services to customers at the remote dispensing pharmacy's location in the area of need, and the remote dispensing pharmacist in charge and supervising pharmacist will not need to be on site at the location. An exact estimate of these benefits is not possible because the resulting benefits will vary widely depending on the characteristics of each supervising pharmacy and each remote dispensing pharmacy, on the number of licensees that these small businesses will employ, and on the approved

location for each remote dispensing pharmacy. Additionally, the data necessary to determine how many remote dispensing pharmacies will be designated by the Division and where those remote dispensing pharmacies might be located is unavailable. Corresponding amendments that define as unprofessional conduct the failure to comply with remote dispensing pharmacy operating standards are not expected to impose any measurable costs for these small businesses. The goal of these provisions is to provide a deterrent such that there is \$0 net impact on all parties involved, and the practices of most businesses are expected to be consistent with practice guidelines. Therefore, any impact from non-compliance will never be uniformly felt across the industry and most small businesses will never be impacted. Further, although a small business disciplined for unprofessional conduct may face financial costs, it is impossible to estimate what those might be both because any such violations are unforeseeable, and because any costs will vary depending on the unique characteristics of the business and the circumstances of the violation. This relevant data is unavailable. None of the remaining proposed changes are expected to impact small businesses' revenues or expenditures because the changes will not alter the price or quantity of any exchanges between any parties, or merely update the rule to establish definitions, clarify standards, encompass current requirements and practices in the profession, and make formatting changes for clarity.

◆ PERSONS OTHER THAN SMALL BUSINESSES, BUSINESSES, OR LOCAL GOVERNMENTAL ENTITIES: First, the proposed amendments that provide operating standards for licensed pharmacists, pharmacy interns, and pharmacy technicians working in a supervising pharmacy or in a remote dispensing pharmacy may affect any of the 4,093 licensed pharmacists, 783 licensed pharmacy interns, and 6,274 licensed pharmacy technicians in Utah. These persons may receive an indirect benefit from potentially increased employment, but this benefit is inestimable because of the unavailability of data. The amendments are also not expected to have any measurable fiscal costs to these persons because they are based on extensive collaboration with the Board, so as to incorporate generally accepted professional standards common in the industry. Second, the proposed amendments allowing pharmacy interns and pharmacy technicians to engage in the administration of vaccines or emergency medications will potentially affect any of the 783 licensed pharmacy interns and 6,274 licensed pharmacy technicians in Utah who choose to provide those services, and these persons may also receive an indirect benefit from potentially increased employment. However, this benefit is inestimable because of the unavailability of data and high cost of conducting research to determine the estimates. Third, the newly added administrative penalty for failure to comply with remote dispensing pharmacy standards is not expected to create a measurable fiscal impact for any licensees because the goal of this rule is to provide a deterrent such that there is a \$0 net impact, so for the typical licensee this fine will have no impact. Inestimable fiscal impacts include any money a person who is adjudicated as having violated the rule might have to pay in the form of an

administrative penalty. This amount is inestimable because it applies only in cases of unforeseeable violations and because any penalty will vary depending on the circumstances of the violation. Finally, pharmacy customers are expected to receive an indirect fiscal benefit from these amendments, resulting from their potentially increased access to pharmacy services and to vaccinations. Customers residing in rural areas and other areas of need within Utah are especially likely to experience a fiscal benefit. However, the precise benefit to these other persons cannot be estimated because of the unavailability of data and the high cost of conducting research to determine the estimates. In sum, although a fiscal benefit to other persons is expected from these amendments from a potential increase in revenue or decrease in costs, the exact impact to other persons is inestimable as it will vary substantially depending on individual characteristics and choices, and the relevant data is unavailable. None of the remaining proposed amendments are expected to impact other persons because they will not alter the price or quantity of any exchanges between any parties, or they merely update the rule to establish definitions, clarify standards, encompass current requirements and practices in the profession, and make formatting changes for clarity.

COMPLIANCE COSTS FOR AFFECTED PERSONS: None of these proposed amendments are expected to impose any compliance costs for any affected persons because the changes will largely save time and money for all parties, and are expected to result in positive fiscal impact or no measurable fiscal impact.

COMMENTS BY THE DEPARTMENT HEAD ON THE FISCAL IMPACT THE RULE MAY HAVE ON BUSINESSES: In accordance with S.B. 170 (2019), this rule filing establishes the scope of practice for pharmacy technicians, and expands their scope to include administering immunizations and emergency medications pursuant to delegation by a pharmacist. Also, in accordance with S.B. 170 (2019), this filing clarifies the requirements and operating standards for the practice of telepharmacy through a remote dispensing pharmacy. This filing also proposes amendments recommended by the Division in collaboration with the Board, including creation of a Committee and clarification of various requirements, including operating standards for a third party logistics provider, required licensee training and education, and required continuing education topics. Various updates and nonsubstantive formatting changes are also made throughout this rule. Small Businesses (less than 50 employees): The amendments to Sections R156-17b-601 and R156-17b-621, allowing pharmacy interns and pharmacy technicians to engage in the administration of vaccines and emergency medications are expected to create a fiscal benefit for the approximately 508 Class A retail pharmacies, 284 Class B pharmacies, and 1,188 Class C pharmacies licensed in Utah that are small businesses (NAICS 446110). The precise fiscal benefit is inestimable because the data necessary to determine how many small business pharmacies will elect to hire pharmacy interns and pharmacy

technicians to provide vaccination services is not available, and because any increase in revenue will vary depending on the characteristics of each small business and on the licensees that the business chooses to employ. The proposed amendments relating to the practice of telepharmacy and remote dispensing pharmacies may impact the approximately 508 Class A retail pharmacies and 284 Class B pharmacies licensed in Utah that are small businesses (NAICS 446110). These amendments are expected to decrease operating costs and increase revenues for Class A pharmacies or Class B pharmacies that choose to serve as supervising pharmacies or are designated as remote dispensing pharmacies. An exact estimate of these benefits is not possible because the resulting benefits will vary widely depending on the characteristics of each supervising pharmacy and each remote dispensing pharmacy, on the number of licensees that these small businesses will employ, and on the approved location for each remote dispensing pharmacy. Additionally, the data necessary to determine how many remote dispensing pharmacies will be designated by the Division and where those remote dispensing pharmacies might be located is unavailable. Amendments that define as unprofessional conduct the failure to comply with remote dispensing pharmacy operating standards are not expected to impose any measurable costs for these small businesses. The goal of these provisions is to provide a deterrent such that there is zero dollar net impact on all parties involved, and the practices of most businesses are expected to be consistent with practice guidelines. Therefore, any impact from non-compliance will never be uniformly felt across the industry and most small businesses will never be impacted. None of the remaining proposed changes are expected to impact small businesses' revenues or expenditures because the changes will not alter the price or quantity of any exchanges between any parties, or the changes merely update the rule to establish definitions, clarify standards, encompass current requirements and practices in the profession, and make formatting changes for clarity. Non-Small Businesses (50 or more employees): The fiscal impact for the approximately 512 Class A retail pharmacies, 286 Class B pharmacies, and 1,188 Class C pharmacies licensed in Utah that are non-small businesses (NAICS 446110) are the same as described above for small businesses. They are either inestimable, for the reasons stated, or there is no fiscal impact.

THE FULL TEXT OF THIS RULE MAY BE INSPECTED, DURING REGULAR BUSINESS HOURS, AT:

COMMERCE  
 OCCUPATIONAL AND PROFESSIONAL  
 LICENSING  
 HEBER M WELLS BLDG  
 160 E 300 S  
 SALT LAKE CITY, UT 84111-2316  
 or at the Office of Administrative Rules.

DIRECT QUESTIONS REGARDING THIS RULE TO:

♦ Jennifer Zaelit by phone at 801-530-7632, or by Internet E-mail at [jzaelit@utah.gov](mailto:jzaelit@utah.gov)

INTERESTED PERSONS MAY PRESENT THEIR VIEWS ON THIS RULE BY SUBMITTING WRITTEN COMMENTS NO LATER THAN AT 5:00 PM ON 11/14/2019

INTERESTED PERSONS MAY ATTEND A PUBLIC HEARING REGARDING THIS RULE:

♦ 10/22/2019 01:30 PM, Heber Wells Bldg, 160 E 300 S, North Conference Room (first floor), Salt Lake City, UT

THIS RULE MAY BECOME EFFECTIVE ON: 11/21/2019

AUTHORIZED BY: Mark Steinagel, Director

**Appendix 1: Regulatory Impact Summary Table\***

Fiscal Costs	FY 2020	FY 2021	FY 2022
State Government	\$763	\$688	\$688
Local Government	\$0	\$0	\$0
Small Businesses	\$0	\$0	\$0
Non-Small Businesses	\$0	\$0	\$0
Other Person	\$0	\$0	\$0
<b>Total Fiscal Costs:</b>	<b>\$763</b>	<b>\$688</b>	<b>\$688</b>
<b>Fiscal Benefits</b>			
State Government	\$0	\$0	\$0
Local Government	\$0	\$0	\$0
Small Businesses	\$0	\$0	\$0
Non-Small Businesses	\$0	\$0	\$0
Other Persons	\$0	\$0	\$0
<b>Total Fiscal Benefits:</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>
<b>Net Fiscal Benefits:</b>	<b>(\$763)</b>	<b>(\$688)</b>	<b>(\$688)</b>

\*This table only includes fiscal impacts that could be measured. If there are inestimable fiscal impacts, they will not be included in this table. Inestimable impacts for State Government, Local Government, Small Businesses and Other Persons are described above. Inestimable impacts for Non-Small Businesses are described below.

**Appendix 2: Regulatory Impact to Non-Small Businesses**

The amendments to Sections R156-17b-601 and R156-17b-621 allowing pharmacy interns and pharmacy technicians to engage in the administration of vaccines and emergency medications are expected to create a fiscal benefit for the approximately 512 Class A retail pharmacies, 286 Class B pharmacies, and 1,188 Class C pharmacies licensed in Utah that are non-small businesses (NAICS 446110). The amended rule will allow these non-small businesses to offer more services and thereby increase their revenue. The precise fiscal benefit is inestimable because the data necessary to determine how many non-small business pharmacies will elect to hire pharmacy interns and pharmacy technicians to provide vaccination services is not available, and because any increase in revenue will vary depending on the characteristics of each non-small businesses and on the licensees that the business chooses to employ.

The proposed amendments relating to the practice of telepharmacy and remote dispensing pharmacies may impact the approximately 512 Class A retail pharmacies and 286 Class B pharmacies licensed in Utah that are non-small businesses (NAICS 446110). These amendments are expected to decrease operating costs and increase revenues for Class A pharmacies or Class B pharmacies that choose to serve as supervising pharmacies or are designated as remote dispensing pharmacies, because these pharmacies will be able to provide services to customers at the remote dispensing pharmacy's location in the area of need, and the remote dispensing pharmacist in charge and supervising pharmacist will not

need to be on site at the location. An exact estimate of these benefits is not possible because the resulting benefits will vary widely depending on the characteristics of each supervising pharmacy and each remote dispensing pharmacy, on the number of licensees that these non-small businesses will employ, and on the approved location for each remote dispensing pharmacy. Additionally, the data necessary to determine how many remote dispensing pharmacies will be designated by the Division and where those remote dispensing pharmacies might be located is unavailable. Corresponding amendments that define as unprofessional conduct the failure to comply with remote dispensing pharmacy operating standards are not expected to impose any measurable costs for these non-small businesses. The goal of these provisions is to provide a deterrent such that there is \$0 net impact on all parties involved, and the practices of most businesses are expected to be consistent with practice guidelines. Therefore, any impact from non-compliance will never be uniformly felt across the industry and most non-small businesses will never be impacted. Further, although a non-small business disciplined for unprofessional conduct may face financial costs, it is impossible to estimate what those might be both because any such violations are unforeseeable, and because any costs will vary depending on the unique characteristics of the business and the circumstances of the violation. This relevant data is unavailable.

None of the remaining proposed changes are expected to impact non-small businesses' revenues or expenditures because the changes will not alter the price or quantity of any exchanges between any parties, or they merely update the rule to establish definitions, clarify standards, encompass current requirements and practices in the profession, and make formatting changes for clarity.

The head of the Department of Commerce, Francine Giani, has reviewed and approved this fiscal analysis.

## **R156. Commerce, Occupational and Professional Licensing.**

### **R156-17b. Pharmacy Practice Act Rule.**

#### **R156-17b-102. Definitions.**

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

(1) "Accredited by ASHP" means a program that:

(a) was accredited by the ASHP on the day the applicant for licensure completed the program; or

(b) was in ASHP candidate status on the day the applicant for licensure completed the program.

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

(3) "Analytical laboratory":

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

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

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

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

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

(c) any area where a demonstration of need is approved by the Division in collaboration with the Board, based on any

factors affecting the access of persons in that area to pharmacy resources.

([4]5) "ASHP" means the American Society of Health System Pharmacists.

([5]6) "Authorized distributor of record" means a pharmaceutical wholesaler with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drugs. An ongoing relationship is deemed to exist between such pharmaceutical wholesaler and a manufacturer, as defined in Section 1504 of the Internal Revenue Code, when the pharmaceutical wholesaler has a written agreement currently in effect with the manufacturer evidencing such ongoing relationship, and the pharmaceutical wholesaler is listed on the manufacturer's current list of authorized distributors of record.

([6]7) "Authorized personnel" means any person who is a part of the pharmacy staff who participates in the operational processes of the pharmacy and contributes to the natural flow of pharmaceutical care.

([7]8) "Chain pharmacy warehouse" means a physical location for prescription drugs that acts as a central warehouse and performs intracompany sales or transfers of the prescription drugs to a group of chain pharmacies that have the same common ownership and control.

([8]9) "Clinic" as used in Subsection 58-17b-625(3)(b) means a class B pharmacy, or a facility which provides out-patient health care services whose primary practice includes the therapeutic use of drugs related to a specific patient for the purpose of:

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

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

(c) arresting or slowing a disease process.

([9]10) "Co-licensed partner" means a person that has the right to engage in the manufacturing or marketing of a co-licensed product.

([10]11) "Co-licensed product" means a device or prescription drug for which two or more persons have the right to engage in the manufacturing, marketing, or both consistent with FDA's implementation of the Prescription Drug Marketing Act as applicable.

([11]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).

([12]13) "Cooperative pharmacy warehouse" means a physical location for drugs that acts as a central warehouse and is owned, operated or affiliated with a group purchasing organization (GPO) or pharmacy buying cooperative and distributes those drugs exclusively to its members.

([13]14) "Counterfeit prescription drug" has the meaning given that term in 21 USC 321(g)(2), including any amendments thereto.

([14]15) "Counterfeiting" means engaging in activities that create a counterfeit prescription drug.

([15]16) "Dispense", as defined in Subsection 58-17b-102(22), does not include transferring medications for a patient from a legally dispensed prescription for that particular patient into a daily or weekly drug container to facilitate the patient taking the correct medication.

([16]17) "Device" means an instrument, apparatus, implement, machine, contrivance, implant, or other similar or related article, including any component part or accessory, which is

required under Federal law to bear the label, "Caution: Federal or State law requires dispensing by or on the order of a physician."

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

(~~18~~19) "DMP designee" means an individual, acting under the direction of a DMP, who:

(a)(i) holds an active health care professional license under one of the following chapters:

- (A) Chapter 67, Utah Medical Practice Act;
- (B) Chapter 68, Utah Osteopathic Medical Practice Act;
- (C) Chapter 70a, Physician Assistant Act;
- (D) Chapter 31b, Nurse Practice Act;
- (E) Chapter 16a, Utah Optometry Practice Act;
- (F) Chapter 44a, Nurse Midwife Practice Act;
- (G) Chapter 17b, Pharmacy Practice Act; or

(ii) is a medical assistant as defined in Subsection 58-67-102 (~~9~~12);

(b) meets requirements established in Subsection 58-17b-803 (4)(c); and

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

(~~19~~20) "DMPIC" means a dispensing medical practitioner licensed under ~~[Section 58-]~~Title 58, Chapter 17b, Part 8 who is designated by a dispensing medical practitioner clinic pharmacy to be responsible for activities of the pharmacy.

(~~20~~21) "Drop shipment" means the sale of a prescription drug to a pharmaceutical wholesaler by the manufacturer of the drug; by the manufacturer's co-licensed product partner, third party logistics provider, or exclusive distributor; or by an authorized distributor of record that purchased the product directly from the manufacturer or from one of these entities; whereby:

(a) the pharmaceutical wholesale distributor takes title to but not physical possession of such prescription drug;

(b) the pharmaceutical wholesale distributor invoices the pharmacy, pharmacy warehouse, or other person authorized by law to dispense to administer such drug; and

(c) the pharmacy, pharmacy warehouse, or other person authorized by law to dispense or administer such drug receives delivery of the prescription drug directly from the manufacturer; from the co-licensed product partner, third party logistics provider, or exclusive distributor; or from an authorized distributor of record that purchases the product directly from the manufacturer or from one of these entities.

(~~21~~22) "Drug therapy management" means the review of a drug therapy regimen of a patient by one or more pharmacists for the purpose of evaluating and rendering advice to one or more practitioners regarding adjustment of the regimen.

(~~22~~23) "Drugs", as used in this rule, means drugs or devices.

(~~23~~24) "Durable medical equipment" or "DME" means equipment that:

- (a) can withstand repeated use;
- (b) is primarily and customarily used to serve a medical purpose;
- (c) generally is not useful to a person in the absence of an illness or injury;

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

(e) may include devices and medical supplies.

(~~24~~25) "Entities under common administrative control" means an entity holds the power, actual as well as legal to influence the management, direction, or functioning of a business or organization.

(~~25~~26) "Entities under common ownership" means entity assets are held indivisibly rather than in the names of individual members.

(~~26~~27) "ExCPT", as used in this rule, means the Exam for the Certification of Pharmacy Technicians.

(~~27~~28) "FDA" means the United States Food and Drug Administration and any successor agency.

(~~28~~29) "FDA-approved" means the federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. Section 301 et seq. and regulations promulgated thereunder permit the subject drug or device to be lawfully manufactured, marketed, distributed, and sold.

(~~29~~30) "High-risk, medium-risk, and low-risk drugs" refers to the risk to a patient's health from compounding sterile preparations, as referred to in USP-NF Chapter 797, for details of determining risk level.

(~~30~~31) "Hospice facility pharmacy" means a pharmacy that supplies drugs to patients in a licensed healthcare facility for terminal patients.

(~~31~~32) "Hospital clinic pharmacy" means a pharmacy that is located in an outpatient treatment area where a pharmacist or pharmacy intern is compounding, admixing, or dispensing prescription drugs, and where:

(a) prescription drugs or devices are under the control of the pharmacist, or the facility for administration to patients of that facility;

(b) prescription drugs or devices are dispensed by the pharmacist or pharmacy intern; or

(c) prescription drugs are administered in accordance with the order of a practitioner by an employee or agent of the facility.

(~~32~~33) "Legend drug" or "prescription drug" means any drug or device that has been determined to be unsafe for self-medication or any drug or device that bears or is required to bear the legend:

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

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

(c) "Rx only".

(~~33~~34) "Long-term care facility" as used in Section 58-17b-610.7 means the same as the term is defined in Section 58-31b-102.

(~~34~~35) "Maintenance medications" means medications the patient takes on an ongoing basis.

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

(~~35~~37) "Manufacturer's exclusive distributor" means an entity that contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer and who takes title to that manufacturer's prescription

drug, but who does not have general responsibility to direct the drug's sale or disposition. Such manufacturer's exclusive distributor shall be licensed as a pharmaceutical wholesaler under this chapter and be an "authorized distributor of record" to be considered part of the "normal distribution channel".

([36]38) "Medical supplies" means items for medical use that are suitable for use in a health care facility or in the home and that are disposable or semi-disposable and are non-reusable.

([37]39) "MPJE" means the Multistate Jurisprudence Examination.

([38]40) "NABP" means the National Association of Boards of Pharmacy.

([39]41) "NAPLEX" means North American Pharmacy Licensing Examination.

([40]42) "Non drug or device handling central prescription processing pharmacy" means a central prescription processing pharmacy that does not engage in compounding, packaging, labeling, dispensing, or administering of drugs or devices.

([41]43) "Normal distribution channel" means a chain of custody for a prescription drug that goes directly, by drop shipment as defined in Subsection ([19]20), or via intracompany transfer from a manufacturer; or from the manufacturer's co-licensed partner, third-party logistics provider, or the exclusive distributor to:

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

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

(c) a cooperative pharmacy warehouse to a pharmacy that is a member of the pharmacy buying cooperative or GPO to a patient;

(d) an authorized distributor of record, and then to either a pharmacy or other designated persons authorized under this chapter to dispense or administer such drug for use by a patient;

(e) an authorized distributor of record, and then to a chain pharmacy warehouse that performs intracompany sales or transfers of such drugs to a group of pharmacies under common ownership and control; or

(f) an authorized distributor of record to another authorized distributor of record to a licensed pharmaceutical facility or a licensed healthcare practitioner authorized under this chapter to dispense or administer such drug for use by a patient.

([42]44) "Other health care facilities" means any entity as defined in Utah Code Subsection 26-21-2(13)(a) or Utah Administrative Code R432-1-3(55).

([43]45) "Parenteral" means a method of drug delivery injected into body tissues but not via the gastrointestinal tract.

([44]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 (40)(a), one of the following facilities:

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

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

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

([45]47) "Pedigree" means a document or electronic file containing information that records each distribution of any given prescription drug.

([46]48) "PIC", as used in this rule, means the pharmacist-in-charge.

([47]49) "Prepackaged" or "Prepackaging" means the act of transferring a drug, manually or by use of an automated pharmacy system, from a manufacturer's or distributor's original container to another container in advance of receiving a prescription drug order or for a patient's immediate need for dispensing by a pharmacy or practitioner authorized to dispense in the establishment where the prepackaging occurred.

([48]50) "Prescription files" means all hard-copy and electronic prescriptions that includes pharmacist notes or technician notes, clarifications or information written or attached that is pertinent to the prescription.

([49]51) "Professional entry degree", as used in Subsection 58-17b-303(1)(f), means the professional entry degree offered by the applicant's ACPE-accredited school or college of pharmacy in the applicant's year of graduation, either a baccalaureate in pharmacy (BSPHarm) or a doctorate in pharmacy (PharmD).

([50]52) "PTCB" means the Pharmacy Technician Certification Board.

([51]53) "Qualified continuing education", as used in this rule, means continuing education that meets the standards set forth in Section R156-17b-309.

([52]54) "Refill" means to fill again.

(55) "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.

(56) "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.

([53]57) "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.

([54]58) "Research facility" means a facility where research takes place that has policies and procedures describing such research.

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

([55]60) "Reverse distributor" means a person or company that retrieves unusable or outdated drugs from a pharmacy for the purpose of removing those drugs from stock and destroying them.

([56]61) "Self-administered hormonal contraceptive" means the same as defined in Subsection 26-62-102(9).

([57]62) "Sterile products preparation facility" means any facility, or portion of the facility, that compounds sterile products using aseptic technique.

(63) "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.

(58)64) "Supervisor" means a licensed pharmacist or DMP in good standing with the Division.

(65) "Telepharmacy system" means a telecommunications and information technologies system that monitors the preparation and dispensing of prescription drugs and provides for related drug review and HIPAA-compliant patient counseling services using:

(a) asynchronous store and forward transfer as defined in Subsection 26-60-102(1);

(b) synchronous interaction as defined in Subsection 26-60-102(6); or

(c) still image capture.

(59)66) "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.

(60)67) "Unauthorized personnel" means any person who is not participating in the operational processes of the pharmacy who in some way would interrupt the natural flow of pharmaceutical care.

(61)68) "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.

(62)69) "Unprofessional conduct", as defined in Title 58, Chapters 1 and 17b, is further defined, in accordance with Subsection 58-1-203(1)(e), in Section R156-17b-502.

(63)70) The "Utah Hormonal Contraceptive Self-screening Risk Assessment Questionnaire", adopted September 18, 2018, by the Division in collaboration with the Utah State Board of Pharmacy and Physicians Licensing Board, as posted on the Division's website, is the self-screening risk assessment questionnaire approved by the Division pursuant to Section 26-62-106.

(64)71) "USP-NF" means the United States Pharmacopeia-National Formulary (USP 41-NF 36), either First Supplement, dated August 1, 2018, or Second Supplement, dated December 1, 2018, which is hereby adopted and incorporated by reference.

(65)72) "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.

(66)73) "Wholesale distribution" means the distribution of drugs to persons other than consumers or patients, but does not include:

(a) intracompany sales or transfers;

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

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

(d) the distribution of drug samples;

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

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

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

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

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

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

#### **R156-17b-105. Licensure - Administrative Inspection.**

In accordance with Subsection 58-17b-103(3)(f), the procedure for disposing of any drugs or devices seized by the Division during an administrative inspection shall be handled as follows:

(1) Any legal drugs or devices found and temporarily seized by the Division that are found to be in compliance with this chapter shall be returned to the PIC, RDPIC, or DMPIC of the pharmacy involved at the conclusion of any investigative or adjudicative proceedings and appeals.

(2) Any drugs or devices that are temporarily seized by the Division that are found to be unlawfully possessed, adulterated, misbranded, outdated, or otherwise in violation of this rule shall be destroyed by Division personnel at the conclusion of any investigative or adjudicative proceedings and appeals. The destruction of any seized controlled substance drugs shall be witnessed by two Division individuals. A controlled substance destruction form shall be completed and retained by the Division.

(3) An investigator may, upon determination that the violations observed are of a nature that pose an imminent peril to the public health, safety and welfare, recommend to the Division Director to issue an emergency licensure action, such as cease and desist.

(4) In accordance with Subsections 58-17b-103(1) and 58-17b-601(1), a secure email address must be established by the PIC, RDPIC, or DMPIC and responsible party for the pharmacy to be used for self-audits or pharmacy alerts initiated by the Division. The PIC, RDPIC or DMPIC and responsible party shall cause the Division's Licensing Bureau to be notified on the applicable form prescribed by the Division of the secure email address or any change thereof within seven days of any email address change. Only one email address shall be used for each pharmacy.

#### **R156-17b-106. Clarification of Use of Shall or May.**

As used in Title 58, Chapters 1 and 17b or this rule, the use of "shall" and "may" is clarified as follows:

(1) "May" is permissive, and is used when granting a right, privilege, or power, or indicating any discretion to act.

(2) "Shall creates a legal duty or obligation on the part of the subject. The statute or rule is mandating that the person act as required by the statute or rule, and the person has no discretion to act differently.

(3) When used negatively:

(a) "may not" is prohibitory, and absolutely prohibits the subject of the statute or rule from performing a particular act; it annihilates discretion; and

(b) "shall not" is a construction not used in drafting Utah statute or rule.

**R156-17b-203. Advisory Pharmacy Compounding Education Committee Created - Membership - Duties.**

(1) In accordance with Subsection 58-1-203(1)(f) and Section R156-1-205, there is created the Advisory Pharmacy Compounding Education Committee ("Committee").

(2) The Committee shall be composed of seven members, who shall be diversified between retail pharmacy, hospital pharmacy, and other pharmacy specialties deemed pertinent by the Division in collaboration with the Board. All members shall have experience and knowledge of least one USP Chapter, USP <795>, USP <797>, or USP <800>.

(3) The Board shall nominate Committee members for appointment in accordance with R156-1-205, and if possible at least six months prior to the date of cessation of service.

(4) The Committee's duties and responsibilities shall be to address pharmacy compounding issues, including:

(a) monitoring current and proposed federal standards and USP standards for pharmacy compounding;

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

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

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

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

(6)(a) The Committee shall annually designate one of its members to act as chair and another member to act as vice chair, on a calendar year basis. The Committee shall elect its chair and vice chair at a meeting conducted in the last quarter of the calendar year.

(b) The chair, vice chair, or their designee shall attend at least one Board meeting per calendar quarter to report the Committee's activities and recommendations to the Division and the Board.

**R156-17b-302. Pharmacy Licensure Classifications - Pharmacist-in-Charge, Remote Dispensing Pharmacist-in-Charge, or Dispensing Medical Practitioner-In-Charge Requirements.**

In accordance with S[ub]section 58-17b-302[(4)], the classification of pharmacies [holding licenses are] is clarified as follows:

(1) A Class A pharmacy includes all retail operations located in Utah[ and requires a PIC]. A Class A pharmacy requires a PIC or RDPIC. Examples of Class A pharmacies include:

(a) retail pharmacies;

(b) mail service retail pharmacies; and

(c) remote dispensing pharmacies.

(2) A Class B pharmacy includes an institutional pharmacy that provides services to a target population unique to the needs of the healthcare services required by the patient. All Class B pharmacies require a PIC, RDPIC, or DMPIC, except for pharmaceutical administration facilities and narcotic treatment program pharmacies. Examples of Class B pharmacies include:

(a) closed door pharmacies;

(b) hospital clinic pharmacies;

(c) narcotic treatment program pharmacies;

(d) nuclear pharmacies;

(e) branch pharmacies;

(f) hospice facility pharmacies;

(g) pharmaceutical administration facility pharmacies;

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

(i) dispensing medical practitioner clinic pharmacies; and

(j) remote dispensing pharmacies.

(3) A Class C pharmacy includes a pharmacy that is involved in:

(a) manufacturing;

(b) producing;

(c) wholesaling;

(d) distributing; or

(e) reverse distributing.

(4) A Class D pharmacy requires a PIC licensed in the state where the pharmacy is located and includes an out-of-state mail [order]service pharmacy. Facilities with multiple locations shall have licenses for each facility and each component part of a facility.

(5) A Class E pharmacy does not require a PIC and includes:

(a) analytical laboratory pharmacies;

(b) animal control pharmacies;

(c) durable medical equipment provider pharmacies;

(d) human clinical investigational drug research facility pharmacies;

(e) medical gas provider pharmacies;

(f) animal narcotic detection training facility pharmacies

(g) third party logistics providers;

(h) non drug or device handling central prescription processing pharmacies; and

(i) veterinarian pharmaceutical facility pharmacies.

(6) [A]The Division shall convert all pharmacy licenses [shall be converted] to the appropriate classification[ by the Division] as identified in Section 58-17b-302.

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

(a) may be the PIC or DMPIC of more than one Class A or Class B pharmacy, if the additional Class A or Class B pharmacies are not open to provide pharmacy services simultaneously; and

(b) may serve as an RDPIC.

(8) A PIC, RDPIC, or DMPIC shall comply with [the provisions of]Section R156-17b-603.

**R156-17b-303a. Qualifications for Licensure - Education Requirements.**

(1) In accordance with Subsections 58-17b-303(2) and 58-17b-304(7)(b), the credentialing agency recognized to provide certification and evaluate equivalency of a foreign educated pharmacy graduate is the Foreign Pharmacy Graduate Examination Committee (FPGEC) of the National Association of Boards of Pharmacy Foundation.

(2) In accordance with Subsection 58-17b-304(7), an applicant for a pharmacy intern license shall demonstrate that ~~he~~the applicant meets one of the following education criteria:

(a) current admission in a ~~[C]~~college of ~~[P]~~pharmacy accredited by the ACPE, by written verification from ~~the Dean~~a dean of the ~~[C]~~college;

(b) a graduate degree from a school or college of pharmacy that is accredited by the ACPE; or

(c) a graduate degree from a foreign pharmacy school as established by a certificate of equivalency from an approved credentialing agency defined in Subsection (1).

(3) In accordance with Subsection 58-17b-305(1)(f), a pharmacy technician shall complete a training program that is:

(a) accredited by ASHP; or

(b) conducted by:

(i) the National Pharmacy Technician Association;

(ii) Pharmacy Technicians University; or

(iii) a branch of the Armed Forces of the United States,

and

(c) meets the following standards:

(i) completion of at least 180 hours of directly supervised practical training in a licensed pharmacy as determined appropriate by a licensed pharmacist in good standing; and

(ii) written protocols and guidelines for the teaching pharmacist outlining the utilization and supervision of pharmacy technician trainees that address:

(A) the specific manner in which supervision will be completed; and

(B) an evaluative procedure to verify the accuracy and completeness of all acts, tasks and functions performed by the pharmacy technician trainee.

(4) An individual shall complete a pharmacy technician training program and successfully pass the required examination as listed in Subsection R156-17b-303c(4) within two years after obtaining a pharmacy technician trainee license, unless otherwise approved by the Division in collaboration with the Board for good cause showing exceptional circumstances.

(a) Unless otherwise approved under Subsection (4), an individual who fails to apply for and obtain a pharmacy technician license within the two-year time frame shall repeat a pharmacy technician training program in its entirety if the individual pursues licensure as a pharmacy technician.

(5)(a) Pharmacy technician training programs that received Division approval on or before April 30, 2014 are exempt from satisfying standards established in Subsection R156-17b-303a(3) for students enrolled on or before December 31, 2018.

(b) A student in a program described in Subsection (5)(a) shall comply with the program completion deadline and testing requirements in Subsection (4), except that the license application shall be submitted to the Division no later than December 31, 2021.

(c) A program in ASHP candidate status shall notify a student prior to enrollment that if the program is denied accreditation status while the student is enrolled in the program, the student will be required to complete education in another program with no assurance of how many credits will transfer to the new program.

(d) A program in ASHP candidate status that is denied accreditation shall immediately notify the Division, enrolled students and student practice sites, of the denial. The notice shall instruct each student and practice site that:

(i) the program no longer satisfies the pharmacy technician license education requirement in Utah; and

(ii) enrollment in a different program meeting requirements established in Subsection R156-17b-303a(3) is necessary for the student to complete training and to satisfy the pharmacy technician license education requirement in Utah.

(6) An applicant from another jurisdiction seeking licensure as a pharmacy technician in Utah is deemed to have met the qualifications for licensure in Subsection 58-17b-305(1)(f) and 58-17b-305(1)(g) if the applicant:

(a) has engaged in the practice of a pharmacy technician for a minimum of 1,000 hours in that jurisdiction within the past two years or has equivalent experience as approved by the Division in collaboration with the Board; and

(b) has passed and maintained current PTCB or ExCPT certification.

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

In accordance with Subsection 58-17b-303(1)(g), the following standards are established for the pharmacy internship required for licensure as a pharmacist:

(1) For graduates of all U.S. pharmacy schools:

(a) At least 1,740 hours of practice supervised by a pharmacy preceptor shall be 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 July 1, 2016 ("Standards 2016"), which is hereby incorporated by reference.

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

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

(2) For graduates of all foreign pharmacy schools, at least 1,440 hours of supervised pharmacy practice in the United States.

(3) Up to 500 hours towards the requirements of Subsections (1)(a) or (2) may be granted, at the discretion of the Division in collaboration with the Board, for other experience substantially related to the practice of pharmacy.

**R156-17b-303c. Qualifications for Licensure - Examinations.**

(1) In accordance with Subsection 58-17b-303(1)(h), the examinations that shall be successfully passed by an applicant for licensure as a pharmacist are:

(a) the NAPLEX with a passing score as established by NABP; and

(b) the Utah Multistate Pharmacy Jurisprudence Examination (MPJE) with a minimum passing score as established by NABP.

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

(3) In accordance with Subsection 58-17b-303(3)(j), an applicant applying by endorsement is required to pass the Utah MPJE.

(4) In accordance with Subsection 58-17b-305(1)(g), an applicant applying for licensure as a pharmacy technician shall pass the PTCB or ExCPT with a passing score as established by the certifying body. The certificate shall exhibit a valid date and that the certification is active.

(5) A graduate of a foreign pharmacy school shall obtain a passing score on the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination.

**R156-17b-304. Temporary Pharmacist Licensure - Additional Authorization to Test.**

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

(a) is:

(i) ~~is~~ a graduate of an ACPE accredited pharmacy school within two months immediately preceding application for licensure;

(ii) enrolled in a pharmacy graduate residency or fellowship program; or

(iii) licensed in good standing to practice pharmacy in another state or territory of the United States;

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

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

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

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

(a) six months from the date of issuance;

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

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

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

(4) A pharmacist temporary license issued in accordance with this section cannot be renewed, but may be extended up to six months, as approved by the Division in collaboration with the Board.

**R156-17b-305. Qualifications for Licensure - Pharmacist by Endorsement.**

~~[(1)]~~In accordance with Subsections 58-17b-303(3) and 58-1-301(3), an applicant for licensure as a pharmacist by endorsement shall:

~~(1)~~ apply through the "Licensure Transfer Program" administered by NABP~~[-]~~;

~~(2)~~ ~~[An applicant for licensure as a pharmacist by endorsement does not need to provide evidence of intern hours if that applicant has:~~

~~(a)~~ lawfully practiced as a licensed pharmacist a minimum of 2,000 hours in the four years immediately preceding application in Utah;

~~(b)~~ have obtained sufficient continuing education credits ~~[required]~~ to maintain a license to practice pharmacy in the state of practice; and

~~(e)~~ not had a pharmacist license suspended, revoked, canceled, surrendered, or otherwise restricted for any reason in any state for ten years prior to application in Utah, unless otherwise approved by the Division in collaboration with the Board.

**R156-17b-307. Qualifications for Licensure - Criminal Background Checks.**

(1) 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-307:

(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.** In accordance with Sections 58-1-308 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 Subsection (3).

(3) An applicant whose license was active and in good standing at the time of expiration may apply for reinstatement

between two years and eight years after the date of expiration, in accordance with the following practice re-entry requirements:

(a) Each applicant shall:

(i) submit a reinstatement application demonstrating compliance with all requirements and conditions of license renewal;

(ii) pay all license renewal and reinstatement fees for the current renewal period; and

(iii) comply with any additional licensure requirements or conditions considered necessary by the Division in collaboration with the Board to protect the public and ensure the applicant is currently competent to engage in the profession, such as:

(A) a background check;

(B) conditional licensure;

(C) refresher or practice re-entry programs;

(D) licensure exams;

(E) supervised practice requirements;

(F) fitness for duty/competency evaluations; or

(G) any other licensure requirements or conditions determined necessary by the Division in collaboration with the Board.

(b) An applicant applying between two and five years after expiration shall also:

(i) if requested, meet with the Board for evaluation of the applicant's qualifications for licensure; and

(ii) submit evidence that the applicant has successfully completed:

(A) all continuing education for each preceding renewal period in which the license was expired; or

(B) a refresher or practice re-entry program approved by the Division in collaboration with the Board.

(c) An applicant applying five or more years after expiration shall also:

(i) meet with the Board for evaluation of the applicant's qualifications for licensure;

(ii) submit evidence that the applicant has:

(A) within five years preceding the application, passed the examinations required for licensure under Section R156-17b-303c (NA[B]PLEX and MPJE for a pharmacist, or PTCB or ExCPT for a pharmacy technician); or

(B) successfully completed a refresher or practice re-entry program approved by the Division in collaboration with the Board; and

(iii) successfully practice under conditional licensure during a period of direct supervision by a pharmacist, for a period equal to at least 40 hours of supervision for each expired year.

(4) The Division in collaboration with the Board may approve 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. Continuing Education.**

In accordance with Section 58-17b-310 and Subsections 58-1-203(1)(g) and 58-1-308(3)(b), the continuing education (CE) requirements for renewal or reinstatement of a pharmacist or pharmacy technician license for each two-year renewal cycle are established as follows:

(1) A pharmacist shall complete at least 30 CE hours, which shall include at minimum:

(a) 12 hours of live or technology-enabled participation in lectures, seminars, or workshops;

(b) 15 hours in one or more of the following topics:

(i) [of]disease state management/drug therapy[;];

(ii) AIDS[~~HHV~~] therapy[;];

(iii) general pharmacy;

(iv) patient safety; or

(v) immunizations[~~or patient safety~~];

(c) one hour of pharmacy law or ethics;

(d) if [providing immunization]engaging in the administration of immunizations or vaccines as defined in Section R156-17b-621, two hours in immunizations or vaccine-related topics, which hours may be counted as part of the 15 hours required under Subsection (1)(b);

(e) if [providing administration of long-acting injectable drug therapy as defined in Section R156-17b-621a, two hours in topics related to long-acting injectables]engaging in the administration of prescription drugs or devices as defined in Section R156-17b-621 or R156-17b-625, two hours in topics related to the administration of those prescription drugs or devices; and

(f) if dispensing a self-administered hormonal contraceptive in accordance with Title 26, Chapter 62, Family Planning Access Act as defined in R156-17b-621b, two hours in topics related to hormonal contraceptive therapy.

(2)(a) A pharmacy technician shall complete at least 20 CE hours, which shall include at minimum:

(i) six hours of live or technology-enabled participation at lectures, seminars, or workshops;[and]

(ii) one hour of pharmacy law or ethics; and

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

([e]b) Current PTCB or ExCPT certification shall fulfill all CE requirements for a pharmacy technician, except for immunization/vaccine-related topic hours that may be required under Subsection (2)(a)(iii).

(3)(a) If a licensee first becomes licensed during the two-year renewal cycle, the licensee's required number of CE hours shall be decreased proportionately according to the date of licensure.

(b) The Division may defer or waive CE requirements as provided in Section R156-1-308d.

(4) CE credit shall be recognized as follows:

(a) One live CE hour for attending one Utah State Board of Pharmacy meeting, up to a maximum of two CE hours during each two-year period. These hours may count as "pharmacy law or ethics" hours.

(b) Two CE hours for each hour of lecturing or instructing a CE course or teaching in the licensee's profession, up to a maximum of ten CE hours during each two-year period. The licensee shall document the course's content and intended audience (e.g., pharmacists, pharmacy technicians, pharmacy interns, physicians, nurses). Public service programs, such as presentations to schoolchildren or service clubs, are not eligible for CE credit.

(c) All CE shall be approved by, conducted by, or under the sponsorship of one of the following:

(i) institutes, seminars, lectures, conferences, workshops, various forms of mediated instruction, and programmed learning courses, presented by an ACPE-approved institution, individual, organization, association, corporation, or agency;

(ii) programs approved by health-related CE approval organizations, provided the CE is nationally recognized by a healthcare accrediting agency and is related to the practice of pharmacy;

(iii) Division training or educational presentations;

(iv) educational meetings that ~~meet~~are ACPE ~~criteria~~accredited and are sponsored by the Utah Pharmacy Association, the Utah Society of Health-System Pharmacists, or other professional organization or association; and

(v) for pharmacists, programs of certification by qualified individuals~~;~~ such as certified diabetes educator credentials, board certification, ~~in advanced therapeutic disease management~~ or other certification as approved by the Division in collaboration with the Board.

(5) A licensee shall maintain documentation sufficient to prove compliance with this section, for a period of four years after the end of the renewal cycle for which the CE is due, by:

(a) maintaining registration with the NABP e-Profile CPE Monitor plan or the NABP CPE Monitor Plus plan; and

(b) maintaining a certificate of completion or other adequate documentation for any CE that cannot be tracked by the licensee's NABP plan.

**R156-17b-402. Administrative Penalties.**

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

TABLE  
FINE SCHEDULE

VIOLATION	FIRST OFFENSE	SUBSEQUENT OFFENSE
58-1-501(1)(a)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
58-1-501(1)(b)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
58-1-501(1)(c)	\$ 500 - \$ 1,000	\$ 1,000 - \$ 5,000
58-1-501(1)(d)	\$ 500 - \$ 1,000	\$ 1,000 - \$ 5,000
58-1-501(1)(e)	\$ 100 - \$ 2,000	\$ 2,000 - \$10,000
58-1-501(1)(f)(i)(A)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
58-1-501(2)(m)(i)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
58-1-501(1)(f)(i)(B)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
58-1-501(2)(m)(ii)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
58-1-501(2)(a)	\$ 100 - \$ 2,000	\$ 2,000 - \$10,000
58-1-501(2)(b)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
58-1-501(2)(c)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
58-1-501(2)(d)	\$ 100 - \$ 500	\$ 200 - \$ 1,000
58-1-501(2)(e)	\$ 100 - \$ 500	\$ 200 - \$ 1,000
58-1-501(2)(f)	\$ 100 - \$ 500	\$ 200 - \$ 1,000
58-1-501(2)(g)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
58-1-501(2)(h)	\$ 100 - \$ 500	\$ 200 - \$ 1,000
58-1-501(2)(i)	\$ 100 - \$ 500	\$ 200 - \$ 1,000
58-1-501(2)(j)	\$ 100 - \$ 500	\$ 200 - \$ 1,000
58-1-501(2)(k)	\$ 100 - \$ 1,000	\$ 500 - \$ 2,000
58-1-501(2)(l)	\$ 100 - \$ 500	\$ 200 - \$ 1,000
58-1-501(2)(n)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
58-1-501.5	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
R156-1-501(1)	\$ 500 - \$ 2,000	\$ 2,500 - \$10,000
R156-1-501(2)	\$ 500 - \$ 2,000	\$ 2,500 - \$10,000
R156-1-501(3)	\$ 500 - \$ 2,000	\$ 2,500 - \$10,000
R156-1-501(4)	\$ 500 - \$ 2,000	\$ 2,500 - \$10,000
R156-1-501(5)	\$ 500 - \$ 2,000	\$ 2,500 - \$10,000
R156-1-501(6)	\$ 500 - \$ 2,000	\$ 2,500 - \$10,000
58-17b-501(1)	\$ 500 - \$ 2,000	\$ 5,000
58-17b-501(2)	\$ 100 - \$ 1,000	\$ 500 - \$ 2,000
58-17b-501(3)(a)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
58-17b-501(3)(b)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000

58-17b-501(4)	\$ 1,000 - \$ 5,000	\$10,000
58-17b-501(5)	\$ 100 - \$ 500	\$ 200 - \$ 1,000
58-17b-501(6)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
58-17b-501(7)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
58-17b-501(8)	\$ 500 - \$ 2,000	\$ 2,500 - \$10,000
58-17b-501(9)	\$ 500 - \$ 1,000	\$ 1,500 - \$ 5,000
58-17b-501(10)	\$ 500 - \$ 2,000	\$ 2,500 - \$10,000
58-17b-501(11)	\$ 500 - \$ 2,000	\$ 2,500 - \$10,000
58-17b-501(12)	\$ 1,000 - \$ 5,000	\$10,000
58-17b-501(13)	\$ 100 - \$ 500	\$ 1,000 - \$ 2,500
58-17b-502(1)(a)	\$ 500 - \$ 2,000	\$ 2,500 - \$10,000
58-17b-502(1)(b)	\$ 2,500 - \$ 5,000	\$ 5,500 - \$10,000
58-17b-502(1)(c)	\$ 1,000 - \$ 5,000	\$10,000
58-17b-502(1)(d)	\$ 500 - \$ 2,000	\$ 2,500 - \$10,000
58-17b-502(1)(e)	\$ 1,000 - \$ 5,000	\$10,000
58-17b-502(1)(f)	\$ 500 - \$ 2,000	\$ 2,500 - \$10,000
58-17b-502(1)(g)	\$ 500 - \$ 2,000	\$ 2,500 - \$10,000
58-17b-502(1)(h)	\$ 100 - \$ 500	\$ 500 - \$ 1,000
58-17b-502(1)(i)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
58-17b-502(1)(j)	\$ 100 - \$ 500	\$ 500 - \$ 1,000
58-17b-502(1)(k)	\$ 100 - \$ 500	\$ 2,000 - \$10,000
58-17b-502(1)(l)	\$ 100 - \$ 500	\$ 500 - \$ 1,000
58-17b-502(1)(m)	\$ 500 - \$ 1,000	\$ 2,500 - \$ 5,000
58-17b-502(1)(n)	\$ 100 - \$ 500	\$ 500 - \$ 1,000
58-17b-502(1)(o)	\$ 100 - \$ 500	\$ 500 - \$ 1,000
R156-17b-502(1)	\$ 250 - \$ 500	\$ 2,000 - \$10,000
R156-17b-502(2)(a)	\$ 250 - \$ 500	\$ 500 - \$ 750
R156-17b-502(2)(b)	\$ 500 - \$ 2,000	\$ 2,500 - \$10,000
R156-17b-502(3)	\$ 100 - \$ 500	\$ 500 - \$ 1,000
R156-17b-502(4)	\$ 50 \$ 100	\$ 200 - \$ 300
R156-17b-502(5)	\$ 100 - \$ 200	\$ 200 - \$ 500
R156-17b-502(6)	\$ 500 - \$ 1,000	\$ 2,000 - \$10,000
R156-17b-502(7)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
R156-17b-502(8)	\$ 100 - \$ 250	\$ 300 - \$ 500
R156-17b-502(9)(a)	\$ 50 - \$ 100	\$ 250 - \$ 500
R156-17b-502(9)(b)	\$ 250 - \$ 500	\$ 750- \$ 1,000
R156-17b-502(10)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
R156-17b-502(11)	\$ 100 - \$ 500	\$ 500 - \$ 1,000
R156-17b-502(12)(a)	\$ 100 - \$ 250	\$ 500 - \$ 2,500
R156-17b-502(12)(b)	\$ 250 - \$ 1,000	\$ 500 - \$ 5,000
R156-17b-502(13)(a)	\$ 50 - \$ 100	\$ 250 - \$ 500
R156-17b-502(13)(b)	\$ 250 - \$ 500	\$ 1,000 - \$ 2,000
R156-17b-502(14)(a)	\$ 500 - \$2,500	\$ 5,000 - \$10,000
R156-17b-502(14)(b)	\$ 2,000 per occurrence	
R156-17b-502(15)	double original penalty, up to	\$10,000
R156-17b-502(16)	\$ 500 - \$2,000	\$ 2,000 - \$10,000
R156-17b-502(17)	\$ 1,000 - \$5,000	\$10,000
R156-17b-502(18)	\$ 500 - \$2,500	\$ 5,000 - \$10,000
R156-17b-502(19)	\$ 100 - \$500	\$ 200 - \$ 1,000
R156-17b-502(20)	\$ 100 - \$500	\$ 200 - \$ 1,000
R156-17b-502(21)	\$ 100 - \$500	\$ 200 - \$ 1,000
R156-17b-502(22)	\$ 500 - \$2,000	\$ 2,000 - \$10,000
R156-17b-502(23)(a)	\$ 100 - \$300	\$ 500 - \$ 1,000
R156-17b-502(23)(b)	\$ 250 - \$500	\$ 500 - \$ 1,250
R156-17b-502(24)	\$ 100 - \$500	\$ 500 - \$ 1,000
R156-17b-502(25)	\$ 500 - \$2,000	\$ 2,500 - \$10,000
R156-17b-502(26)	\$ 500 - \$2,000	\$ 2,500 - \$10,000
58-37-8	\$ 1,000 - \$5,000	\$ 5,000 - \$10,000
R156-37-502(1)(a)	\$ 500 - \$2,000	\$ 2,500 - \$10,000
R156-37-502(1)(b)	\$ 500 - \$2,000	\$ 2,500 - \$10,000
R156-37-502(2)	\$ 500 - \$2,000	\$ 2,500 - \$10,000
R156-37-502(3)	\$ 500 - \$2,000	\$ 2,500 - \$10,000
R156-37-502(4)	\$ 500 - \$2,000	\$ 2,500 - \$10,000
R156-37-502(5)	\$ 500 - \$2,000	\$ 2,500 - \$10,000
R156-37-502(6)	\$ 500 - \$2,000	\$ 2,500 - \$10,000
R156-37-502(7)	\$ 500 - \$2,000	\$ 2,500 - \$10,000
R156-37-502(8)	\$ 500 - \$2,000	\$ 2,500 - \$10,000
Any other conduct that constitutes Unprofessional or Unlawful conduct	\$ 100 - \$ 500	\$ 200 - \$ 1,000

~~\_\_\_\_\_ (1) preventing or refusing to permit any authorized agent of the Division to conduct an inspection, in violation of Subsection 58-17b-501(1):~~

~~\_\_\_\_\_ initial offense: \$500 – \$2,000  
\_\_\_\_\_ subsequent offense(s): \$5,000~~

~~\_\_\_\_\_ (2) failing to deliver the license or permit or certificate to the Division upon demand, in violation Subsection 58-17b-501(2):~~

~~\_\_\_\_\_ initial offense: \$100 – \$1,000  
\_\_\_\_\_ subsequent offense(s): \$500 – \$2,000~~

~~\_\_\_\_\_ (3) using the title pharmacist, druggist, pharmacy intern, pharmacy technician, pharmacy technician trainee or any other term having a similar meaning or any term having similar meaning when not licensed to do so, in violation of Subsection 58-17b-501(3)(a):~~

~~\_\_\_\_\_ initial offense: \$500 – \$2,000  
\_\_\_\_\_ subsequent offense(s): \$2,000 – \$10,000~~

~~\_\_\_\_\_ (4) conducting or transacting business under a name that contains as part of that name the words drugstore, pharmacy, drugs, medicine store, medicines, drug shop, apothecary, prescriptions or any other term having a similar meaning or in any manner advertising otherwise describing or referring to the place of the conducted business or profession when not licensed to do so, in violation of Subsection 58-17b-501(3)(b):~~

~~\_\_\_\_\_ initial offense: \$500 – \$2,000  
\_\_\_\_\_ subsequent offense(s): \$2,000 – \$10,000~~

~~\_\_\_\_\_ (5) buying, selling, causing to be sold, or offering for sale any drug or device that bears the inscription sample, not for resale, investigational purposes, or experimental use only or other similar words inspection, in violation of Subsection 58-17b-501(4):~~

~~\_\_\_\_\_ initial offense: \$1,000 – \$5,000  
\_\_\_\_\_ subsequent offense(s): \$10,000~~

~~\_\_\_\_\_ (6) using to the licensee's own advantage or revealing to anyone other than the Division, Board or its authorized representatives, any information acquired under the authority of this chapter concerning any method or process that is a trade secret, in violation of Subsection 58-17b-501(5):~~

~~\_\_\_\_\_ initial offense: \$100 – \$500  
\_\_\_\_\_ subsequent offense(s): \$200 – \$1,000~~

~~\_\_\_\_\_ (7) illegally procuring or attempting to procure any drug for the licensee or to have someone else procure or attempt to procure a drug, in violation of Subsection 58-17b-501(6):~~

~~\_\_\_\_\_ initial offense: \$500 – \$2,000  
\_\_\_\_\_ subsequent offense(s): \$2,000 – \$10,000~~

~~\_\_\_\_\_ (8) filling, refilling or advertising the filling or refilling of prescription drugs when not licensed to do so, in violation of Subsection 58-17b-501(7):~~

~~\_\_\_\_\_ initial offense: \$500 – \$2,000  
\_\_\_\_\_ subsequent offense(s): \$2,000 – \$10,000~~

~~\_\_\_\_\_ (9) requiring any employed pharmacist, pharmacy intern, pharmacy technician, pharmacy technician trainee or authorized supportive personnel to engage in any conduct in violation of this chapter, in violation of Subsection 58-17b-501(8):~~

~~\_\_\_\_\_ initial offense: \$500 – \$2,000  
\_\_\_\_\_ subsequent offense(s): \$2,500 – \$10,000~~

~~\_\_\_\_\_ (10) being in possession of a drug for an unlawful purpose, in violation of Subsection 58-17b-501(9):~~

~~\_\_\_\_\_ initial offense: \$500 – \$1,000  
\_\_\_\_\_ subsequent offense(s): \$1,500 – \$5,000~~

~~\_\_\_\_\_ (11) dispensing a prescription drug to anyone who does not have a prescription from a practitioner or to anyone who is known or should be known as attempting to obtain drugs by fraud or misrepresentation, in violation of Subsection 58-17b-501(10):~~

~~\_\_\_\_\_ initial offense: \$500 – \$2,000  
\_\_\_\_\_ subsequent offense(s): \$2,500 – \$10,000~~

~~\_\_\_\_\_ (12) selling, dispensing or otherwise trafficking in prescription drugs when not licensed to do so or when not exempted from licensure, in violation of Subsection 58-17b-501(11):~~

~~\_\_\_\_\_ initial offense: \$1,000 – \$5,000  
\_\_\_\_\_ subsequent offense(s): \$10,000~~

~~\_\_\_\_\_ (13) using a prescription drug or controlled substance for the licensee that was not lawfully prescribed for the licensee by a practitioner, in violation of Subsection 58-17b-501(12):~~

~~\_\_\_\_\_ initial offense: \$100 – \$500  
\_\_\_\_\_ subsequent offense(s): \$1,000 – \$2,500~~

~~\_\_\_\_\_ (14) willfully deceiving or attempting to deceive the Division, the Board or its authorized agents as to any relevant matter regarding compliance under this chapter, in violation of Subsection 58-17b-502(1):~~

~~\_\_\_\_\_ initial offense: \$500 – \$2,000  
\_\_\_\_\_ subsequent offense(s): \$2,500 – \$10,000~~

~~\_\_\_\_\_ (15) paying rebates to practitioners or any other health care provider, or entering into any agreement with a medical practitioner or any other person for the payment or acceptance of compensation for recommending the professional services of either party, in violation of Subsection 58-17b-502(2):~~

~~\_\_\_\_\_ initial offense: \$2,500 – \$5,000  
\_\_\_\_\_ subsequent offense(s): \$5,500 – \$10,000~~

~~\_\_\_\_\_ (16) misbranding or adulteration of any drug or device or the sale, distribution or dispensing of any outdated, misbranded, or adulterated drugs or devices, in violation of Subsection 58-17b-502(3):~~

~~\_\_\_\_\_ initial offense: \$1,000 – \$5,000  
\_\_\_\_\_ subsequent offense(s): \$10,000~~

~~\_\_\_\_\_ (17) engaging in the sale or purchase of drugs that are samples or packages bearing the inscription "sample" or "not for resale" or similar words or phrases, in violation of Subsection 58-17b-502(4):~~

~~\_\_\_\_\_ initial offense: \$500 – \$2,000  
\_\_\_\_\_ subsequent offense(s): \$2,500 – \$10,000~~

~~\_\_\_\_\_ (18) accepting back and redistributing any unused drugs, with the exception as provided in Section 58-17b-503, in violation of Subsection 58-17b-502(5):~~

~~\_\_\_\_\_ initial offense: \$1,000 – \$5,000  
\_\_\_\_\_ subsequent offense(s): \$10,000~~

~~\_\_\_\_\_ (19) engaging in an act in violation of this chapter committed by a person for any form of compensation if the act is incidental to the person's professional activities, including the activities of a pharmacist, pharmacy intern, pharmacy technician, or pharmacy technician trainee in violation of Subsection 58-17b-502(6):~~

~~\_\_\_\_\_ initial offense: \$500 – \$2,000  
\_\_\_\_\_ subsequent offense(s): \$2,500 – \$10,000~~

~~\_\_\_\_\_ (20) violating Federal Title II, PL 91, Controlled Substances Act or Title 58, Chapter 37, Utah Controlled Substances Act, or rules and regulations adopted under either act, in violation~~

of Subsection 58-17b-502(7):

initial offense: \$500 – \$2,000

subsequent offense(s): \$2,500 – \$10,000

(21) requiring or permitting pharmacy interns, pharmacy technicians, or pharmacy technician trainees to engage in activities outside the scope of practice for their respective license classifications, or beyond their scopes of training and ability, in violation of Subsection 58-17b-502(8):

initial offense: \$100 – \$500

subsequent offense(s): \$500 – \$1,000

(22) administering without appropriate training, guidelines, lawful order, or in conflict with a practitioner's written guidelines or protocol for administering, in violation of Subsection 58-17b-502(9):

initial offense: \$500 – \$2,000

subsequent offense(s): \$2,000 – \$10,000

(23) disclosing confidential patient information in violation of the provision of the Health Insurance Portability and Accountability Act of 1996 or other applicable law, in violation of Subsection 58-17b-502(10):

initial offense: \$100 – \$500

subsequent offense(s): \$500 – \$1,000

(24) engaging in the practice of pharmacy without a licensed pharmacist designated as the PIC, in violation of Subsection 58-17b-502(11):

initial offense: \$100 – \$500

subsequent offense(s): \$2,000 – \$10,000

(25) failing to report to the Division any adverse action taken by another licensing jurisdiction, government agency, law enforcement agency or court, in violation of Subsection 58-17b-502(12):

initial offense: \$100 – \$500

subsequent offense(s): \$500 – \$1,000

(26) preparing a prescription drug in a dosage form that is regularly and commonly available from a manufacturer in quantities and strengths prescribed by a practitioner, in violation of Subsection 58-17b-502(13):

initial offense: \$500 – \$1,000

subsequent offense(s): \$2,500 – \$5,000

(27) failing to act in accordance with Title 26, Chapter 62, Family Planning Access Act, when dispensing a self-administered hormonal contraceptive under a standing order, in violation of Subsection 58-17b-502(14):

initial offense: \$100 – \$500

subsequent offense(s): \$500 – \$1,000

(28) violating any ethical code provision of the American Pharmaceutical Association Code of Ethics for Pharmacists, October 27, 1994, in violation of Subsection R156-17b-502(1):

initial offense: \$250 – \$500

subsequent offense(s): \$2,000 – \$10,000

(29) failing to comply with USP-NF Chapter 795 guidelines, in violation of Subsection R156-17b-502(2):

initial offense: \$250 – \$500

subsequent offense(s): \$500 – \$750

(30) failing to comply with USP-NF Chapter 797 guidelines, in violation of Subsection R156-17b-502(2):

initial offense: \$500 – \$2,000

subsequent offense(s): \$2,500 – \$10,000

(31) failing to comply with the continuing education requirements set forth in this rule, in violation of Subsection R156-17b-502(3):

initial offense: \$100 – \$500

subsequent offense(s): \$500 – \$1,000

(32) failing to provide the Division with a current mailing address within 10 days following any change of address, in violation of Subsection R156-17b-502(4):

initial offense: \$50 – \$100

subsequent offense(s): \$200 – \$300

(33) defaulting on a student loan, in violation of Subsection R156-17b-502(5):

initial offense: \$100 – \$200

subsequent offense(s): \$200 – \$500

(34) failing to abide by all applicable federal and state law regarding the practice of pharmacy, in violation of Subsection R156-17b-502(6):

initial offense: \$500 – \$1,000

subsequent offense(s): \$2,000 – \$10,000

(35) failing to comply with administrative inspections, in violation of Subsection R156-17b-502(7):

initial offense: \$500 – \$2,000

subsequent offense(s): \$2,000 – \$10,000

(36) failing to return a self-inspection report according to the deadline established by the Division, or providing false information on a self-inspection report, in violation of Subsection R156-17b-502(8):

initial offense: \$100 – \$250

subsequent offense(s): \$300 – \$500

(37) violating the laws and rules regulating operating standards in a pharmacy discovered upon inspection by the Division, in violation of Subsection R156-17b-502(9):

initial violation: \$50 – \$100

failure to comply within determined time: \$250 – \$500

subsequent violations: \$250 – \$500

failure to comply within established time: \$750 – \$1,000

(38) abandoning a pharmacy and/or leaving drugs accessible to the public, in violation of Subsection R156-17b-502(10):

initial offense: \$500 – \$2,000

subsequent offense(s): \$2,000 – \$10,000

(39) failing to identify license classification when communicating by any means, in violation of Subsection R156-17b-502(11):

initial offense: \$100 – \$500

subsequent offense(s): \$500 – \$1,000

(40) failing to maintain an appropriate ratio of personnel, in violation of Subsection R156-17b-502(12):

Pharmacist initial offense: \$100 – \$250

Pharmacist subsequent offense(s): \$500 – \$2,500

Pharmacy initial offense: \$250 – \$1,000

Pharmacy subsequent offense(s): \$500 – \$5,000

(41) allowing any unauthorized persons in the pharmacy, in violation of Subsection R156-17b-502(13):

Pharmacist initial offense: \$50 – \$100

Pharmacist subsequent offense(s): \$250 – \$500

Pharmacy initial offense: \$250 – \$500

Pharmacy subsequent offense(s): \$1,000 – \$2,000

~~(42) failing to offer to counsel any person receiving a prescription medication, in violation of Subsection R156-17b-502(14):~~

~~Pharmacy personnel initial offense: \$500 - \$2,500~~

~~Pharmacy personnel subsequent offense(s): \$5,000 - \$10,000~~

~~Pharmacy: \$2,000 per occurrence~~

~~(43) failing to pay an administrative fine within the time designated by the Division, in violation of Subsection R156-17b-502(15):~~

~~Double the original penalty amount up to \$10,000~~

~~(44) failing to comply with the PIC or DMPIC standards as established in Section R156-17b-603, in violation of Subsection R156-17b-502(16):~~

~~initial offense: \$500 - \$2,000~~

~~subsequent offense(s) \$2,000 - \$10,000~~

~~(45) failing to take appropriate steps to avoid or resolve identified drug therapy management problems as referenced in Subsection R156-17b-611(3), in violation of Subsection R156-17b-502(17):~~

~~initial offense: \$500 - \$2,500~~

~~subsequent offense: \$5,000 - \$10,000~~

~~(46) dispensing a medication that has been discontinued by the FDA, in violation of Subsection R156-17b-502(18):~~

~~initial offense: \$100 - \$500~~

~~subsequent offense: \$200 - \$1,000~~

~~(47) failing to keep or report accurate records of training hours, in violation of Subsection R156-17b-502(19):~~

~~initial offense: \$100 - \$500~~

~~subsequent offense: \$200 - \$1,000~~

~~(48) failing to provide PIC or DMPIC information to the Division within 30 days of a change in PIC or DMPIC, in violation of Subsection R156-17b-502(20):~~

~~initial offense: \$100 - \$500~~

~~subsequent offense: \$200 - \$1,000~~

~~(49) requiring a pharmacy, PIC, or any other pharmacist to operate a pharmacy with unsafe personnel ratio, in violation of Subsection R156-17b-502(21):~~

~~initial offense: \$500 - \$2,000~~

~~subsequent offense: \$2,000 - \$10,000~~

~~(50) failing to update the Division within seven calendar days of any change in the email address designated for use in self-audits or pharmacy alerts, in violation of Subsection R156-17b-502(22):~~

~~Pharmacist initial offense: \$100 - \$300~~

~~Pharmacist subsequent offense(s): \$500 - \$1,000~~

~~Pharmacy initial offense: \$250 - \$500~~

~~Pharmacy subsequent offense(s): \$500 - \$1,250~~

~~(51) practicing or attempting to practice as a pharmacist, pharmacist intern, pharmacy technician, or pharmacy technician trainee or operating a pharmacy without a license, in violation of Subsection 58-1-501(1)(a):~~

~~initial offense: \$500 - \$2,000~~

~~subsequent offense(s): \$2,000 - \$10,000~~

~~(52) impersonating a licensee or practicing under a false name, in violation of Subsection 58-1-501(1)(b):~~

~~initial offense: \$500 - \$2,000~~

~~subsequent offense(s): \$2,000 - \$10,000~~

~~(53) knowingly employing an unlicensed person, in violation of Subsection 58-1-501(1)(c):~~

~~initial offense: \$500 - \$1,000~~

~~subsequent offense(s): \$1,000 - \$5,000~~

~~(54) knowingly permitting the use of a license by another person, in violation of Subsection 58-1-501(1)(d):~~

~~initial offense: \$500 - \$1,000~~

~~subsequent offense(s): \$1,000 - \$5,000~~

~~(55) obtaining a passing score, applying for or obtaining a license or otherwise dealing with the Division or Board through the use of fraud, forgery, intentional deception, misrepresentation, misstatement, or omission, in violation of Subsection 58-1-501(1)(e):~~

~~initial offense: \$100 - \$2,000~~

~~subsequent offense(s): \$2,000 - \$10,000~~

~~(56) issuing a prescription without prescriptive authority conferred by a license or an exemption to licensure, in violation of Subsection 58-1-501(1)(f)(i)(A) and 58-1-501(2)(m)(i):~~

~~initial offense: \$500 - \$2,000~~

~~subsequent offense(s): \$2,000 - \$10,000~~

~~(57) issuing a prescription without prescriptive authority conferred by a license or an exemption to licensure without obtaining information sufficient to establish a diagnosis, identify underlying conditions and contraindications to treatment in a situation other than an emergency or an on-call cross coverage situation, in violation of Subsection 58-1-501(1)(f)(i)(B) and 58-1-501(2)(m)(ii):~~

~~initial offense: \$500 - \$2,000~~

~~subsequent offense(s): \$2,000 - \$10,000~~

~~(58) violating or aiding or abetting any other person to violate any statute, rule or order regulating pharmacy, in violation of Subsection 58-1-501(2)(a):~~

~~initial offense: \$100 - \$2,000~~

~~subsequent offense(s): \$2,000 - \$10,000~~

~~(59) violating or aiding or abetting any other person to violate any generally accepted professional or ethical standard, in violation of Subsection 58-1-501(2)(b):~~

~~initial offense: \$500 - \$2,000~~

~~subsequent offense(s): \$2,000 - \$10,000~~

~~(60) engaging in conduct that results in conviction of, or a plea of nolo contendere, or a plea of guilty or nolo contendere held in abeyance to a crime, in violation of Subsection 58-1-501(2)(e):~~

~~initial offense: \$500 - \$2,000~~

~~subsequent offense(s): \$2,000 - \$10,000~~

~~(61) engaging in conduct that results in disciplinary action by any other jurisdiction or regulatory authority, that if the conduct had occurred in this state, would constitute grounds for denial of licensure or disciplinary action, in violation of Subsection 58-1-501(2)(d):~~

~~initial offense: \$100 - \$500~~

~~subsequent offense(s): \$200 - \$1,000~~

~~(62) engaging in conduct, including the use of intoxicants, drugs, or similar chemicals, to the extent that the conduct does or may impair the ability to safely engage in practice as a pharmacist, pharmacy intern, pharmacy technician, or pharmacy technician trainee, in violation of Subsection 58-1-501(2)(e):~~

~~initial offense: \$100 – \$500~~  
~~subsequent offense(s): \$200 – \$1,000~~  
~~(63) practicing or attempting to practice as a pharmacist, pharmacy intern, pharmacy technician, or pharmacy technician trainee when physically or mentally unfit to do so, in violation of Subsection 58-1-501(2)(f):~~  
~~initial offense: \$100 – \$500~~  
~~subsequent offense(s): \$200 – \$1,000~~  
~~(64) practicing or attempting to practice as a pharmacist, pharmacy intern, pharmacy technician, or pharmacy technician trainee through gross incompetence, gross negligence or a pattern of incompetency or negligence, in violation of Subsection 58-1-501(2)(g):~~  
~~initial offense: \$500 – \$2,000~~  
~~subsequent offense(s): \$2,000 – \$10,000~~  
~~(65) practicing or attempting to practice as a pharmacist, pharmacy intern, pharmacy technician, or pharmacy technician trainee by any form of action or communication that is false, misleading, deceptive or fraudulent, in violation of Subsection 58-1-501(2)(h):~~  
~~initial offense: \$100 – \$500~~  
~~subsequent offense(s): \$200 – \$1,000~~  
~~(66) practicing or attempting to practice as a pharmacist, pharmacy intern, pharmacy technician, or pharmacy technician trainee beyond the individual's scope of competency, abilities or education, in violation of Subsection 58-1-501(2)(i):~~  
~~initial offense: \$100 – \$500~~  
~~subsequent offense(s): \$200 – \$1,000~~  
~~(67) practicing or attempting to practice as a pharmacist, pharmacy intern, pharmacy technician, or pharmacy technician trainee beyond the scope of licensure, in violation of Subsection 58-1-501(2)(j):~~  
~~initial offense: \$100 – \$500~~  
~~subsequent offense(s): \$200 – \$1,000~~  
~~(68) verbally, physically or mentally abusing or exploiting any person through conduct connected with the licensee's practice, in violation of Subsection 58-1-501(2)(k):~~  
~~initial offense: \$100 – \$1,000~~  
~~subsequent offense(s): \$500 – \$2,000~~  
~~(69) acting as a supervisor without meeting the qualification requirements for that position as defined by statute or rule, in violation of Subsection 58-1-501(2)(l):~~  
~~initial offense: \$100 – \$500~~  
~~subsequent offense(s): \$200 – \$1,000~~  
~~(70) violating a provision of Section 58-1-501.5, in violation of Subsection 58-1-501(2)(n):~~  
~~initial offense: \$500 – \$2,000~~  
~~subsequent offense(s): \$2,000 – \$10,000~~  
~~(71) surrendering licensure to any other licensing or regulatory authority having jurisdiction over the licensee or applicant in the same occupation or profession while an investigation or inquiry into allegations of unprofessional or unlawful conduct is in progress or after a charging document has been filed against the applicant or licensee alleging unprofessional or unlawful conduct, in violation of Subsection R156-1-501(1):~~  
~~initial offense: \$500 – \$2,000~~  
~~subsequent offense(s): \$2,500 – \$10,000~~  
~~(72) practicing a regulated occupation or profession in, through, or with a limited liability company that has omitted the~~

~~words, "limited company," "limited liability company," or the abbreviation "L.C." or "L.L.C." in the commercial use of the name of the limited liability company, in violation of Subsection R156-1-501(2):~~  
~~initial offense: \$500 – \$2,000~~  
~~subsequent offense(s): \$2,500 – \$10,000~~  
~~(73) practicing a regulated occupation or profession in, through, or with a limited partnership that has omitted the words, "limited partnership," "limited," or the abbreviation "L.P." or "Ltd." in the commercial use of the name of the limited partnership, in violation of Subsection R156-1-501(3):~~  
~~initial offense: \$500 – \$2,000~~  
~~subsequent offense(s): \$2,500 – \$10,000~~  
~~(74) practicing a regulated occupation or profession in, through, or with a professional corporation that has omitted the words "professional corporation" or the abbreviation "P.C." in the commercial use of the name of the professional corporation, in violation of Subsection R156-1-501(4):~~  
~~initial offense: \$500 – \$2,000~~  
~~subsequent offense(s): \$2,500 – \$10,000~~  
~~(75) using a capitalized DBA (doing-business-as name) that has not been properly registered with the Division of Corporations and with the Division of Occupational and Professional Licensing, in violation of Subsection R156-1-501(5):~~  
~~initial offense: \$500 – \$2,000~~  
~~subsequent offense(s): \$2,500 – \$10,000~~  
~~(76) failing, as a prescribing practitioner, to follow the "Model Policy for the Use of Controlled Substances to Follow the Treatment of Pain," May 2004, established by the Federation of State Medical Boards of the United States, Inc., which is hereby adopted and incorporated by reference, in violation of R156-1-501(6):~~  
~~initial offense: \$500 – \$2,000~~  
~~subsequent offense(s): \$2,500 – \$10,000~~  
~~(77) engaging in prohibited acts as defined in Section 58-37-8, in violation of Section 58-37-8:~~  
~~initial offense: \$1,000 – \$5,000~~  
~~subsequent offense(s): \$5,000 – \$10,000~~  
~~(78) self-prescribing or self-administering by a licensee of any Schedule II or Schedule III controlled substance that is not prescribed by another practitioner having authority to prescribe the drug, in violation of Subsection R156-37-502(1)(a):~~  
~~initial offense: \$500 – \$2,000~~  
~~subsequent offense(s): \$2,500 – \$10,000~~  
~~(79) prescribing or administering a controlled substance for a condition that the licensee is not licensed or competent to treat, in violation of Subsection R156-37-502(1)(b):~~  
~~initial offense: \$500 – \$2,000~~  
~~subsequent offense(s): \$2,500 – \$10,000~~  
~~(80) violating any federal or state law relating to controlled substances, in violation of Subsection R156-37-502(2):~~  
~~initial offense: \$500 – \$2,000~~  
~~subsequent offense(s): \$2,500 – \$10,000~~  
~~(81) failing to deliver to the Division all controlled substance certificates issued by the Division, to the Division, upon an action that revokes, suspends, or limits the license, in violation of R156-37-502(3):~~  
~~initial offense: \$500 – \$2,000~~  
~~subsequent offense(s): \$2,500 – \$10,000~~

~~(82) failing to maintain controls over controlled substances that would be considered by a prudent licensee to be effective against diversion, theft, or shortage of controlled substances, in violation of Subsection R156-37-502(4):~~

~~initial offense: \$500 - \$2,000~~

~~subsequent offense(s): \$2,500 - \$10,000~~

~~(83) being unable to account for shortages of controlled substances in any controlled substances inventory for which the licensee has responsibility, in violation of Subsection R156-37-502(5):~~

~~initial offense: \$500 - \$2,000~~

~~subsequent offense(s): \$2,500 - \$10,000~~

~~(84) knowingly prescribing, selling, giving away, or administering, directly or indirectly, or offering to sell, furnish, give away, or administer any controlled substance to a drug dependent person, as defined in Subsection 58-37-2(1)(s), except for legitimate medical purposes as permitted by law, in violation of Subsection R156-37-502(6):~~

~~initial offense: \$500 - \$2,000~~

~~subsequent offense(s): \$2,500 - \$10,000~~

~~(85) refusing to make available for inspection controlled substance stock, inventory, and records as required under this rule or other law regulating controlled substances and controlled substance records, in violation of Subsection R156-37-502(7):~~

~~initial offense: \$500 - \$2,000~~

~~subsequent offense(s): \$2,500 - \$10,000~~

~~(86) failing to submit controlled substance prescription information to the database manager after being notified in writing to do so, in violation of Subsection R156-37-502(8):~~

~~initial offense: \$500 - \$2,000~~

~~subsequent offense(s): \$2,500 - \$10,000~~

~~(87) any other conduct that constitutes unprofessional or unlawful conduct:~~

~~initial offense: \$100 - \$500~~

~~subsequent offense(s): \$200 - \$1,000~~

~~(88) if licensed as a DMP or DMP clinic pharmacy, delegating the dispensing of a drug to a DMP designee who has not completed a formal or on-the-job dispensing training program that meets standards established in Section R156-17b-622, in violation of Subsection R156-17b-502(25):~~

~~initial offense: \$500 - \$2,000~~

~~subsequent offense: \$2,500 - \$10,000]~~

### **R156-17b-502. Unprofessional Conduct.**

"Unprofessional conduct" includes:

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

(2)(a) failing to comply with the USP-NF Chapter[s] 795 [and 797] if [such chapters are] applicable to activities performed [in the pharmacy];

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

(3) failing to comply with the continuing education requirements set forth in these rules;

(4) failing to provide the Division with a current mailing address within a 10 business day period of time following any change of address;

(5) defaulting on a student loan;

(6) failing to abide by all applicable federal and state law regarding the practice of pharmacy;

(7) failing to comply with administrative inspections;

(8) failing to return according to the deadline established by the Division, or providing false information on a self-inspection report;

(9)(a) violating the laws and rules regulating operating standards in a pharmacy discovered upon inspection by the Division;

(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;

(10) abandoning a pharmacy or leaving prescription drugs accessible to the public;

(11) failing to identify licensure classification when communicating by any means;

(12)(a) as a pharmacist,[-] practicing pharmacy with an inappropriate pharmacist to pharmacy intern ratio established by Subsection R156-17b-606(1)(d) or pharmacist to pharmacy technician trainee ratio as established by Subsection R156-17b-601(3)5];

(b) as a pharmacy, practicing pharmacy with an inappropriate pharmacist to pharmacy intern ratio established by Subsection R156-17b-606(1)(d) or pharmacist to pharmacy technician trainee ratio as established by Subsection R156-17b-601(5);

(13)(a) as a pharmacist,[-] allowing any unauthorized persons in the pharmacy;

(b) as a pharmacy, allowing any unauthorized persons in the pharmacy;

(14)(a) as a pharmacist,[-] failing to offer to counsel any person receiving a prescription medication;

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

(15) failing to pay an administrative fine that has been assessed in the time designated by the Division;

(16) failing to comply with the PIC or DMPIC standards as established in Section R156-17b-603;

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

(18) failing to take appropriate steps to avoid or resolve identified drug therapy management problems as referenced in Subsection R156-17b-611(3);

(19) dispensing medication that has been discontinued by the FDA;

(20) failing to keep or report accurate records of training hours;

(21) failing to provide PIC or DMPIC information to the Division within 30 days of a change in PIC or DMPIC;

(22) requiring a pharmacy, pharmacist, or DMP to operate the pharmacy or allow 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)(a) ~~as a pharmacist,[-] failing to update the Division within seven calendar days of any change in the email address designated for use in self-audits or pharmacy alerts;~~

(b) as a pharmacy, failing to update the Division within seven calendar days of any change in the email address designated for use in self-audits or pharmacy alerts;

(24) 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 that meets standards established in Section R156-17b-622; ~~[-and]~~

(25) failing to make a timely report regarding dispensing of an opiate antagonist to the division and to the physician who issued the standing order as required in Section R156-17b-625; ~~and~~

(26) failing to comply with the operating standards for a remote dispensing pharmacy as established in Section R156-17b-614g.

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

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

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

- (a) receiving written prescriptions;
- (b) taking refill orders, 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 ~~[-as referenced in Subsection 58-17b-102(56)];~~

(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 [left]saved on voicemail for a pharmacist to review;

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

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

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

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

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

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

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

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

(B) process for supervising technicians who check medications;

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

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

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

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

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

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

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

(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 a prescription drug.

~~([4]3) [Pharmacy technicians shall have general supervision by a pharmacist in accordance with Subsection R156-17b-603(3)(s).]A pharmacy technician may administer vaccines and emergency medications pursuant to delegation by a pharmacist under the Vaccine Administration Protocol: Standing Order to Administer Immunizations and Emergency Medications, adopted March 26, 2019, by the Division in collaboration with the Utah State Board of Pharmacy and Utah Physicians Licensing Board, as posted on the Division website, 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 R156-1-102a(4)(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 R156-17-309.

([5]4) A pharmacy technician trainee;

(a) shall practice only under the direct supervision of a pharmacist, and in a ratio not to exceed one pharmacy technician trainee to one pharmacist; 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)(l).

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

A pharmacy intern may provide services including the practice of pharmacy under the supervision of an approved preceptor, as defined in Subsection 58-17b-102(50), provided the pharmacy intern met the criteria as established in Subsection R156-17b-~~306~~303a.

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

(1) The PIC, RDPIC, or DMPIC shall have the responsibility to oversee the operation of the pharmacy in conformance with all laws and rules pertinent to the practice of pharmacy and the distribution of drugs, durable medical equipment, and medical supplies. The PIC, RDPIC, or DMPIC shall be personally in full and actual charge of the pharmacy.

(2) In accordance with Subsections 58-17b-103(1) and 58-17b-601(1), a unique email address shall be established by the PIC, RDPIC, DMPIC, or responsible party for the pharmacy to be used for self-audits or pharmacy alerts initiated by the Division. The PIC, RDPIC, DMPIC, or responsible party shall notify the Division of the pharmacy's email address in the initial application for licensure.

(3) The duties of the PIC, RDPIC, or DMPIC shall include:

(a) assuring 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) assuring 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) assuring 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) assuring 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 all materials, including drugs, chemicals and biologicals;

(j) maintenance of records of all transactions of the pharmacy necessary to maintain accurate control over and accountability for all pharmaceutical materials required by applicable state and federal laws and regulations;

(k) establishment and maintenance of effective controls against theft or diversion of prescription drugs and records for such drugs;

(l) if records are kept on a data processing system, the maintenance of records stored in that system shall be in compliance with pharmacy requirements;

(m) legal operation of the pharmacy including meeting all inspection and other requirements of all 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) assuring that all relevant information is submitted to the Controlled Substance Database in the appropriate format and in a timely manner;

(q) assuring that all pharmacy personnel have the appropriate licensure;

(r) assuring 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) assuring that the PIC, RDPIC, or DMPIC assigned to the pharmacy is recorded with the Division and that the Division is notified of a change in PIC, RDPIC, or DMPIC within 30 days of the change; and

(t) assuring, with regard to the unique email address used for self-audits and pharmacy alerts, that:

(i) the pharmacy uses a single email address; and

(ii) the pharmacy notifies the Division, on the form prescribed, of any change in the email address within seven calendar days of the change.

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

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

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

- (a) the name, address and DEA registration number of the pharmacy;
- (b) the anticipated date of closing;
- (c) the name, address and DEA registration number of the pharmacy acquiring the controlled substances; and
- (d) the date the transfer of controlled substances will occur.

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

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

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

- (a) return prescription drugs to manufacturer or supplier for credit or disposal; or
- (b) transfer, sell or give away prescription drugs to a person who is legally entitled to possess drugs, such as a hospital or another pharmacy.

(4) If the pharmacy dispenses prescription drug orders:

- (a) transfer the prescription drug order files, including refill information and patient medication records, to a licensed pharmacy within a reasonable distance of the closing pharmacy; and
- (b) move all signs or notify the landlord or owner of the property that it is unlawful to use the word "pharmacy", or any other word or combination of words of the same or similar meaning, or any graphic representation that would mislead or tend to mislead the public that a pharmacy is located at this address.

(5) Within ~~[40]~~ten days of the closing of the pharmacy, the PIC, RDPIC, or DMPIC shall forward to the Division a written notice of the closing that includes the following information:

- (a) the actual date of closing;
- (b) a surrender of the license issued to the pharmacy;
- (c) a statement attesting:
  - (i) that an inventory as specified in Subsection R156-17b-605(4) has been conducted; and
  - (ii) the manner in which the legend drugs and controlled substances possessed by the pharmacy were transferred or disposed;
- (d) if the pharmacy dispenses prescription drug orders, the name and address of the pharmacy to which the prescription drug orders, including refill information and patient medication records, were transferred.

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

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

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

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

(8) If the PIC, 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 the provisions of this section.

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

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

(1) All out of date legend drugs and controlled substances shall be removed from the inventory at regular intervals and in correlation to the beyond use date imprinted on the label.

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

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

(b) the inventory records shall be maintained for a period of five years and be readily available for inspection;

(c) the inventory records shall be filed separately from all other records;

(d) the inventory records shall be in a written, typewritten, or printed form and include all stocks of controlled substances on hand on the date of the inventory including any that are out of date drugs and drugs in automated pharmacy systems. An inventory taken by use of a verbal recording device shall be promptly transcribed;

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

(f) the person taking the inventory and the PIC, RDPIC, or DMPIC shall indicate the time the inventory was taken and shall sign and date the inventory with the date the inventory was taken. The signature of the PIC, RDPIC, or DMPIC and the date of the inventory shall be documented within 72 hours or three working days of the completed initial, annual, change of ownership and closing inventory;

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

(h) the person taking the inventory shall make an estimated count or measure of all Schedule III, IV or V controlled substances, unless the container holds more than 1,000 tablets or capsules in which case an exact count of the contents shall be made;

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

(j) if the pharmacy maintains a perpetual inventory of any of the drugs required to be inventories, the perpetual inventory shall be reconciled on the date of the inventory.

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

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

(b) in the event a pharmacy commences business with no controlled substances on hand, the pharmacy shall record this fact as the initial inventory. An inventory reporting no Schedule I and II controlled substances shall be listed separately from an inventory reporting no Schedule III, IV, and V controlled substances;

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

(d) when combining two pharmacies, each pharmacy shall:

(i) conduct a separate closing pharmacy inventory of controlled substances on the date of closure; and

(ii) conduct a combined opening inventory of controlled substances for the new pharmacy prior to opening.

(4) Requirement for annual controlled substances inventory shall be within 12 months following the inventory date of each year and may be taken within four days of the specified inventory date and shall include all stocks including out-of-date drugs and drugs in automated pharmacy systems.

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

(a) a pharmacy that changes ownership shall take an inventory of all legend drugs and controlled substances including out-of-date drugs and drugs in automated pharmacy systems on the date of the change of ownership;

(b) such inventory shall constitute, for the purpose of this section, the closing inventory for the seller and the initial inventory for the buyer; and

(c) transfer of Schedule I and II controlled substances shall require the use of official DEA order forms (Form 222).

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

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

**R156-17b-607. Operating Standards - Supportive Personnel.**

(1) In accordance with Subsection 58-17b-102(~~69~~71) (a), supportive personnel may assist in any tasks not related to drug preparation or processing including:

- (a) stock ordering and restocking;
- (b) cashiering;
- (c) billing;

(d) filing;

(e) receiving a written prescription and delivering it to the pharmacist, pharmacy intern, pharmacy technician, pharmacy technician trainee, DMP, or DMP designee;

(f) housekeeping; and

(g) delivering a pre-filled prescription to a patient.

(2) Supportive personnel shall not enter information into a patient prescription profile or accept verbal refill information.

(3) In accordance with Subsection 58-17b-102(~~69~~71)(b) all supportive personnel shall be under the supervision of a licensed pharmacist or DMP. The licensed pharmacist or DMP shall be present in the area where the person being supervised is performing services and shall be immediately available to assist the person being supervised in the services being performed except for the delivery of pre-filled prescriptions as provided in Subsection (1)(g) above.

(4) In accordance with Subsection 58-17b-601(1), a pharmacist, pharmacy intern, pharmacy technician, pharmacy technician trainee, DMP, or DMP designee whose license has been revoked or is suspended shall not be allowed to provide any support services in a pharmacy.

**R156-17b-608. Common Carrier Delivery.**

A pharmacy that employs the United States Postal Service or other common carrier to deliver a filled prescription directly to a patient shall, under the direction of the PIC, RDPIC, DMPIC, or other responsible employee:

(1) use adequate storage or shipping containers and shipping processes to ensure drug stability and potency. The shipping processes shall include the use of appropriate packaging material and devices, according to the recommendations of the manufacturer or the United States Pharmacopeia Chapter 1079, in order to ensure that the drug is kept at appropriate storage temperatures throughout the delivery process to maintain the integrity of the medication;

(2) use shipping containers that are sealed in a manner to detect evidence of opening or tampering;

(3) develop and implement policies and procedures to ensure accountability, safe delivery, and compliance with temperature requirements. The policies and procedures shall address when drugs do not arrive at their destination in a timely manner or when there is evidence that the integrity of a drug was compromised during shipment. In these instances, the pharmacy shall make provisions for the replacement of the drugs;

(4)(i) provide for an electronic, telephonic, or written communication mechanism for a pharmacy to offer counseling to the patient as defined in Section 58-17b-613; and

(ii) provide documentation of such counseling; and

(5) provide information to the patient indicating what the patient should do if the integrity of the packaging or drug was compromised during shipment.

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

In accordance with Subsection 58-17b-601(1), guidelines for providing patient counseling established in Section 58-17b-613 include the following:

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

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

(2) A pharmacy facility shall orally offer to counsel, but ~~[shall not be]~~ is not required to counsel a patient or patient's agent ~~[when the patient or patient's agent]~~ who refuses such counseling.

(3) Based upon the professional judgment of the pharmacist, pharmacy intern, or DMP, patient counseling may include the following elements:

- (a) the name and description of the prescription drug;
- (b) the dosage form, dose, route of administration and duration of drug therapy;
- (c) intended use of the drug, when known, and expected action;
- (d) special directions and precautions for preparation, administration and use by the patient;
- (e) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
- (f) techniques for self-monitoring drug therapy;
- (g) proper storage;
- (h) prescription refill information;
- (i) action to be taken in the event of a missed dose;
- (j) pharmacist comments relevant to the individual's drug therapy, including any other information specific to the patient or drug; and

(k) the date after which the prescription should not be taken or used, or the beyond use date.

(4) The offer to counsel shall be documented, ~~[and said d]~~ Documentation shall be [available to the Division. These records shall be] maintained for a period of five years, and be available for inspection by the Division within 7-10 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 ~~[at the patient's]~~ or other designated location, ~~[the following is applicable]~~:

(a) the information specified in Subsection (3) ~~[of this section]~~ shall be delivered with the dispensed prescription in writing;

(b) if prescriptions are routinely delivered outside the area covered by the pharmacy's local telephone service, the pharmacist shall place on the prescription container or on a separate sheet delivered with the prescription container, the telephone number of the pharmacy and the statement "Written information about this prescription has been provided for you. Please read this information before you take this medication. If you have questions concerning this prescription, a pharmacist is available during normal business hours to answer these questions."; and

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

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

(8) A pharmacist or pharmacy intern who dispenses a self-administered hormonal contraceptive shall obtain a completed Utah Hormonal Contraceptive Self-Screening Risk Assessment Questionnaire and provide written information and counseling as described in Section 26-62-106.

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

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

(1) Prescription orders for controlled substances (including prescription transfers) shall be handled according to the rules of the Federal Drug Enforcement Administration.

(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 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) Prescriptions for legend drugs having a remaining authorization for refill may be transferred by the pharmacist, pharmacy intern, or DMP at the pharmacy holding the prescription to a pharmacist, pharmacy intern 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). The transferring pharmacist, pharmacy intern, or DMP and receiving pharmacist, pharmacy intern, or DMP shall act diligently to ensure that the total number of authorized refills is not exceeded. The following additional terms apply to such a transfer:

(a) the transfer shall be communicated directly between pharmacists, pharmacy interns, or DMP or as authorized under Subsection R156-17b-613(9);

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

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

(i) indicate on the prescription record that 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, or DMP to whom such prescription is transferred; and

(E) the name of the pharmacist, pharmacy intern, or DMP transferring the prescription drug order information;

(e) 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) a pharmacist, pharmacy intern, or DMP may not refuse to transfer original prescription information to another pharmacist, pharmacy intern, 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) 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) Refills may be dispensed only in accordance with the prescriber's authorization as indicated on the original prescription drug order;

(8) If there are no refill instructions on the original prescription drug order, or if all 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) Refills of prescription drug orders for legend drugs may not be refilled after one year 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) Refills of prescription drug orders for controlled substances shall be done in accordance with Subsection 58-37-6(7) (f).

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

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

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

(~~b~~) 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 [~~should be~~] documented and [~~said~~]the documentation [~~should be~~]available to the Division upon request;

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

(~~d~~) [~~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 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~~) the pharmacist or DMP;

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

(~~ii~~) [~~the pharmacist or DMP~~]informs the practitioner of the emergency refill at the earliest reasonable time;

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

(~~iv~~) [~~the pharmacist or DMP~~]affixes a label to the dispensing container as specified in Section 58-17b-602. [~~]~~

(~~12~~) If the prescription was originally filled at another pharmacy, the pharmacist or DMP may exercise his professional judgment in refilling the prescription provided:

(a) the patient has the prescription container label, receipt or other documentation from the other pharmacy that contains the essential information;

(b) 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;

(~~e~~) the pharmacist or DMP, in his or her professional judgment, determines that such a request for an emergency refill is appropriate and meets the requirements of (a) and (b) of this subsection; and

(~~d~~) the pharmacist or DMP complies with the requirements of Subsections (11)(e) through (g) of this section.

(~~13~~)12 The address specified in Subsection 58-17b-602(1)(b) shall be a physical address, not a post office box.

(~~14~~)13 In accordance with Subsection 58-37-6(7)(e), 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.

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

In accordance with Subsections 58-17b-102(29) [~~through~~]and (30), 58-17b-602(1), R156-82, and R156-1, prescription orders may be issued by electronic means of communication according to the following standards:

(1) Prescription orders for Schedule II - V controlled substances received by electronic means of communication shall be handled according to Part 1304.04 of Section 21 of the CFR.

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

(a) all electronically transmitted prescription orders shall include the following:

(i) all 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) the prescription order shall be transmitted under the direct supervision of the prescribing practitioner or his designated agent;

(c) the pharmacist or DMP shall exercise professional judgment regarding the accuracy and authenticity of the transmitted prescription. Practitioners or their agents transmitting medication orders using electronic equipment are to provide voice verification when requested by the pharmacist receiving the medication order. The pharmacist or DMP is responsible for assuring that each electronically transferred prescription order is valid and 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;

(d) a practitioner may authorize an agent to electronically transmit a prescription provided that the identifying information of the transmitting agent is included on the transmission. The practitioner's electronic signature, or other secure method of validation, shall be provided with the electronic prescription; and

(e) an electronically transmitted prescription order that meets the requirements above shall be deemed to be the original prescription.

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

(4) No agreement between a prescribing practitioner and a pharmacy shall require that prescription orders be transmitted by electronic means from the prescribing practitioner to that pharmacy only.

(5) The pharmacist or DMP shall retain a 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.

(6) Wholesalers, distributors, manufacturers, pharmacists and pharmacies shall not supply electronic equipment to any prescriber for transmitting prescription orders.

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

(8) Prescription orders electronically transmitted to the pharmacy by the patient shall not be filled or dispensed.

(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 by law or by the prescriber by electronic transmission providing the pharmacies share a real-time, on-line database provided that:

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

(b) 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.

**R156-17b-614a. Operating Standards - Class A or Class B Pharmacy - General Operating Standards~~[, Class A and B Pharmacy]~~.**

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

~~(1)~~ The general operating standards include:

(a) ~~[shall]~~ be well lighted, well ventilated, clean and sanitary;

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

(c) be equipped to permit the orderly storage of prescription drugs and durable medical equipment in a manner to permit clear identification, separation and easy retrieval of products and an environment necessary to maintain the integrity of the product inventory;

(d) be equipped to permit practice within the standards and ethics of the profession as dictated by the usual and ordinary scope of practice to be conducted within that facility;

(e) be stocked with the quality and quantity of product necessary for the facility to meet its scope of practice in a manner consistent with the public health, safety and welfare; ~~[and]~~

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

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

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

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

~~(h) have a counseling area to allow for confidential patient counseling, if applicable.~~

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

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

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

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

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

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

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

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

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

(i) official or assigned name;

(ii) strength;

(iii) dosage form of the preparation;

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

(v) description of all ingredients and their quantities;

(vi) compatibility and stability information, including references when available;

(vii) equipment needed to prepare the preparation;

(viii) mixing instructions, which shall include:

(A) order of mixing;

(B) mixing temperatures or other environmental controls;

(C) duration of mixing; and

(D) other factors pertinent to the replication of the preparation as compounded;

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

(A) generic name and quantity or concentration of each active ingredient;

(B) assigned beyond use date;

(C) storage conditions; and

(D) prescription or control number, whichever is applicable;

(x) container used in dispensing;

(xi) packaging and storage requirements;

(xii) description of final preparation; and

(xiii) quality control procedures and expected results.

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

(i) official or assigned name;

(ii) strength and dosage of the preparation;

(iii) Master Formulation Record reference for the preparation;

(iv) names and quantities of all components;

(v) sources, lot numbers, and expiration dates of components;

(vi) total quantity compounded;

(vii) name of the person who prepared the preparation;

(viii) name of the compounder who approved the preparation;

(ix) name of the person who performed the quality control procedures;

(x) date of preparation;

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

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

(A) active ingredients;

(B) beyond-use-date;

(C) storage conditions; and

(D) lot number;

(xiv) proof of the duplicate labeling information, which proof shall:

(A) be kept at the pharmacy;

(B) be immediately retrievable;

(C) include an audit trail for any altered form; and

(D) be reproduced in:

(I) the original format that was dispensed;

(II) an electronic format; or

(III) a scanned electronic version;

(xvii) description of final preparation;

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

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

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

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

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

(iii) quantity;

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

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

(vi) device-specific instructions, where appropriate.

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

(i) generic name and quantity or concentration of each active ingredient. In the instance of a sterile preparation for

parenteral use, labeling shall include the name and base solution for infusion preparation;

(ii) assigned compounding record or lot number; and

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

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

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

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

(B) manufacturer recommendations; and

(C) reliable, published research;

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

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

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

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

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

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

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

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

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

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

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

Act;

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

(i) Code of Federal Regulations (CFR) 21, Food and Drugs, Part 1300 to end or equivalent such as the USP DI Drug Reference Guides;

(j) current FDA Approved Drug Products (orange book); and

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

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

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

~~(7)~~ A pharmacy ~~shall~~ 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.

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

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

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

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

(~~12~~) A pharmacist, DMP or other responsible individual shall verify that controlled substances are listed on the suppliers' invoices and were actually received by clearly recording their initials and the actual date of receipt of the controlled substances.

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

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

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

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

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

In accordance with Subsection 58-17b-601(1), the following operating standards apply to 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:

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

(b) have a written contract outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of said contract; and

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

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

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

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

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

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

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

(3) "Non drug or device handling central prescription processing pharmacies", as defined in Subsection R156-17b-102([37]40), shall be licensed as Class E pharmacies. 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.**

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

(1) A remote dispensing pharmacy shall:

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

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

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

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

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

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

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

(b) complete identifying information concerning the proposed RDPIC;

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

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

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

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

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

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

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

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

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

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

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

(vii) requiring monthly in-person inspections of the remote dispensing pharmacy and appropriate documentation by the RDPIC; and

(viii) any additional policies and procedures required by Subsection R156-17b-614f(2) for Central Prescription Processing.

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

(6) Staffing and Supervision.

(a) In accordance with Subsections 58-17b-612(1)(b) and (d):

(i) a supervising pharmacist may not supervise more than two remote dispensing pharmacies simultaneously; and

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

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

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

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

(e) Adequate supervision by a supervising pharmacist of a remote dispensing pharmacy shall include maintaining uninterrupted visual supervision and auditory communication with the site, and full supervisory control of the automated system, if applicable. This supervision may not be delegated to any other person.

(7) The supervising pharmacy shall maintain a telepharmacy system that provides for effective video and audio communication between supervising pharmacy personnel and remote dispensing pharmacy personnel and patients, that:

\_\_\_\_\_ (a) provides an adequate number of views of the entire site;

\_\_\_\_\_ (b) facilitates adequate pharmacist supervision;

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

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

\_\_\_\_\_ (e) is secure and HIPAA compliant as defined in R156-17b-102(64).

\_\_\_\_\_ (8) Each component of the telepharmacy system shall be in good working order. If any component of the system is malfunctioning, the remote dispensing pharmacy shall immediately close to the public and remain closed until system corrections or repairs are completed, unless a pharmacist is present onsite.

\_\_\_\_\_ (9) The supervising pharmacy shall develop and include in both the supervising pharmacy's and the remote dispensing pharmacy's policies and procedures a plan for continuation of pharmaceutical services by the remote dispensing pharmacy in case of an emergency interruption:

\_\_\_\_\_ (a) The plan shall address the timely arrival at the remote dispensing pharmacy of necessary personnel, and the delivery to the remote dispensing pharmacy of necessary supplies, within a reasonable period of time following the identification of an emergency need. A supervising pharmacist shall be available onsite at the remote dispensing pharmacy as soon as possible after an emergency, and shall notify the Division in writing if the time exceeds 24 hours.

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

\_\_\_\_\_ (10) Facility.

\_\_\_\_\_ (a) The remote dispensing pharmacy's security system shall allow for tracking of entries into the remote dispensing pharmacy and the RDPIC shall periodically review the record of entries.

\_\_\_\_\_ (b) A remote dispensing pharmacy shall display a sign easily visible to the public that informs patients of the following:

\_\_\_\_\_ (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.

\_\_\_\_\_ (11) Records and Inspections.

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

\_\_\_\_\_ (ii) Electronic records shall be available to and accessible from both the remote dispensing pharmacy and the supervising pharmacy.

\_\_\_\_\_ (iii) The original records of the controlled substance prescriptions dispensed from the remote dispensing pharmacy shall be maintained at the remote dispensing pharmacy.

\_\_\_\_\_ (b) The remote dispensing pharmacy shall retain a recording of surveillance, excluding patient communications, for at least 45 days.

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

\_\_\_\_\_ (i) maintenance and reconciliation of all controlled substances;

\_\_\_\_\_ (ii) a perpetual inventory of Schedule II controlled substances;

\_\_\_\_\_ (iii) temperature logs of the refrigerator and freezer that hold medications; and

\_\_\_\_\_ (iv) the RDPIC's periodic review of the record of entries into the remote dispensing pharmacy.

**R156-17b-615. Operating Standards - Class C Pharmacy - Pharmaceutical Wholesaler/Distributor and Pharmaceutical Manufacturer.**

In accordance with Subsections 58-17b-102(47) and 58-17b-601(1), the operating standards for Class C pharmacies designated as pharmaceutical wholesaler/distributor and pharmaceutical manufacturer licensees includes the following:

(1) Each pharmaceutical wholesaler or manufacturer that distributes or manufactures drugs or medical devices in Utah shall be licensed by the Division. A separate license shall be obtained for each separate location engaged in the distribution or manufacturing of prescription drugs. Business names cannot be identical to the name used by another unrelated wholesaler licensed to purchase drugs and devices in Utah.

(2) 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.

(3) An applicant for licensure as a pharmaceutical wholesale distributor shall provide the following minimum information:

(a) All trade or business names used by the licensee (including "doing business as" and "formerly known as");

(b) Name of the owner and operator of the license 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) 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 related to prescription drugs;

(c) is employed by the applicant 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, sick leave and vacation leave; and

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

(5) The licensee shall provide the name, business address, and telephone number of a person to serve as the designated representative for each facility of the pharmaceutical wholesaler that engages in the distribution of drugs or devices.

(6) All pharmaceutical wholesalers and manufacturer shall publicly display or have readily available all licenses and the most recent inspection report administered by the Division.

(7) 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) 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 local building codes, life and safety codes and control access to persons to ensure unauthorized entry is not made;

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

(d) be well lighted on the outside perimeter;

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

(f) be equipped with security measures, systems and procedures necessary to provide reasonable security against theft and diversion of prescription drugs or alteration or tampering with computers and records pertaining to prescription drugs or prescription drug precursors.

(9) Each facility shall provide the storage of prescription drugs, prescription drug precursors, and prescription drug devices in accordance with 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 devices, the products 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) Each person 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 dispensing or administering the prescription drug. 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) 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) licensee under this Act and pharmacies or other persons 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) 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) 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(~~19~~20)(c) and R156-17b-615(~~43~~), 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) 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 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 to whom distribution is made to include 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) 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 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) 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, 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, other appropriate party or appropriately destroyed;

(e) a procedure for providing for documentation of 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 suspected of being counterfeit, contraband, or suspect of being contraband) and reporting of such discrepancies within three (3) business days to the Division and/or 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) 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 in charge which lists shall include 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) permitting the state licensing authority and authorized federal, state and local law enforcement officials, upon presentation of proper credentials, to enter and inspect their premises and delivery vehicles and to audit their records and written operating policies and procedures, at reasonable times and in a reasonable manner, to the extent authorized by law; and

(c) obtaining a controlled substance license from the Division and registering with the Drug Enforcement Administration

(DEA) if they engage 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 ~~shall~~ 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:

([a]i) are under the same ownership;

([b]ii) have processes and systems for separating and securing all aspects of the operation; and

([e]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 ~~Order~~Service Pharmacies.**

(1) In accordance with 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 physical facility, records and operations.

(2) An out of state mail ~~order~~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 ~~Operating Standards~~- General Provisions.**

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

(a) the identity of the supervisor or director;

(b) a detailed plan of care;

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

(d) 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-617g. Operating Standards - Class E Pharmacy - Third Party Logistics Provider.**

(1) A third party logistics provider shall comply with storage practices for facilitating, including:

~~(a) access to warehouse space of suitable size to facilitate safe operations, including a suitable area to quarantine suspect product;~~

~~(b) adequate security; and~~

~~(c) written policies and procedures to:~~

~~(i) address receipt, security, storage, inventory, shipment, and distribution of a product;~~

~~(ii) identify, record, and report confirmed losses or thefts in the United States;~~

~~(iii) correct errors and inaccuracies in inventories;~~

~~(iv) provide support for manufacturer recalls;~~

~~(v) prepare for, protect against, and address any reasonably foreseeable crisis that affects security or operation at the facility, such as a strike, fire, or flood;~~

~~(vi) ensure that any expired product is segregated from other products and returned to the manufacturer or reverse distributor;~~

~~(vii) maintain the capability to trace the receipt and outbound distribution of a product, and supplies and records of inventory; and~~

~~(viii) quarantine or destroy a suspect product if directed to do so by the respective manufacturer, wholesale distributor, dispenser, or an authorized government agency.~~

~~(2) 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-621. Operating Standards - Pharmacist, Pharmacy Intern, and Pharmacy Technician Administration - Training.**

~~[(1)—]In accordance with Subsections 58-17b-102(53), (56), and (57), and 58-17b-502(1)(i); [~~58-17b-502(9);~~]~~

~~(1) A pharmacist or pharmacy intern who will administer a prescription drug or device shall complete the following appropriate training prior to engaging in administration [~~for the administration of a prescription drug includes~~]:~~

~~(a) current Basic Life Support (BLS) certification; [~~and~~~~

~~(b) successful completion of a training program which includes at a minimum:~~

~~(i) b) for injectable drugs, didactic and practical training for administering injectable drugs;~~

~~(c) topics related to the specific prescription drug or device that will be administered;~~

~~(ii) d) [~~the current Advisory Committee on Immunization Practices (ACIP) of the United States Center for Disease Control and Prevention guidelines for the administration of immunizations~~]if administering vaccines, current guidelines from the Advisory Committee on Immunization Practices (ACIP) of the U.S. Centers for Disease Control and Prevention (CDC); and~~

~~(iii) e) the management of an anaphylactic reaction.~~

~~(2) A pharmacy technician who will administer a prescription drug or device shall complete the appropriate training described in Subsections (1)(a), (b), and (c) prior to engaging in administration.~~

~~[(2)3] Sources for the appropriate training include:~~

~~(a) ACPE approved programs; [~~and~~~~

~~(b) curriculum-based programs from an ACPE accredited college of pharmacy, or an ASHP accredited pharmacy technician program;~~

~~(c) state or local health department programs; and~~

~~(d) other Board recognized providers.~~

~~[(3)4] [Training is to be supplemented by documentation of two hours of continuing education related to the area of practice in each preceding renewal period.]An individual who engages in the administration of prescription drugs or devices shall:~~

~~(a) maintain documentation that they obtained their required training; and~~

~~(b) for each renewal cycle after their initial training, complete at least two hours of continuing education related to their administration of prescription drugs or devices, in accordance with Section R156-17b-309.~~

~~[(4)5] The "Vaccine Administration Protocol: Standing Order to Administer Immunizations and Emergency Medications", adopted March [27, 2012]26, 2019, by the Division in collaboration with the Utah State Board of Pharmacy and the Utah Physicians Licensing Board, as posted on the Division website, is the guideline or standard for pharmacist administration of vaccines and emergency medications, and for pharmacy intern or pharmacy technician administration pursuant to delegation by a pharmacist.~~

**R156-17b-621a. Operating Standards - Pharmacist Administration of a Long-acting Injectable Drug Therapy - Training.**

~~In accordance with Subsections 58-17b-502(9)1(i) and 58-17b-625(2):~~

~~(1) [Training for a pharmacist to administer long-acting injectables intramuscularly shall include successful completion of]Prior to engaging in the administration of 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 long-acting injectable[s] drugs intramuscularly shall:~~

~~(a) maintain documentation that [~~the~~]they obtained their required training [~~was obtained~~]prior to any administration; and~~

~~(b) for each renewal cycle after the initial training, successfully complete [~~a minimum of~~]at least two hours of continuing education related to administering long-acting injectable[s] drugs, in accordance with Section R156-17b-309.~~

**R156-17b-621b. Operating Standards - Pharmacist and Pharmacy Intern Dispensing of a Self-Administered Hormonal Contraceptive - Training.**

~~In accordance with Subsection 58-17b-502([44]n) and Section 26-[62]64-106:~~

~~(1) Prior to dispensing a self-administered hormonal contraceptive, a pharmacist or pharmacy intern shall successfully complete a training program for dispensing self-administered hormonal contraceptives that is provided by an ACPE-accredited provider and approved by the Division in collaboration with the Board.~~

~~(2) A pharmacist or pharmacy intern who engages in the dispensing of a self-administered hormonal contraceptive shall:~~

~~(a) maintain documentation that [~~the~~]they obtained their required training [~~was obtained~~]prior to any dispensing; and~~

(b) for each renewal cycle after the initial training, successfully complete a minimum of two hours of continuing education related to dispensing a self-administered hormonal contraceptive, in accordance with Section R156-17b-309.

(3) The Utah Hormonal Contraceptive Self-screening Risk Assessment Questionnaire, adopted September 18, 2018, posted on the Division's website, is the self-screening risk assessment questionnaire to be used for pharmacist and pharmacy intern dispensing of self-administered hormonal contraceptives.

**R156-17b-622. Standards - Dispensing Training Program.**

(1) In accordance with Subsection R156-17b-102 ([47]18), 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.**

~~[(1) A cosmetic]The drugs that may be dispensed by a DMP in accordance with Subsection 58-17b-802(1) and Section 58-17b-803 [is]are limited to:~~

- ~~(1) the following cosmetic drugs:~~
- ~~(a) Latisse; and~~
- ~~(b) the injectable weight loss drug human chorionic gonadotropin; and~~

~~(2) the legend, non-controlled drugs approved under Section R156-83-306 for prescribing by an online prescriber.[~~

~~(2) An injectable weight loss drug that may be dispensed by a DMP in accordance with Section 58-17b-803 is limited to human chorionic gonadotropin.]~~

**KEY: pharmacists, licensing, pharmacies**  
**Date of Enactment or Last Substantive Amendment:**  
**[December 27, 2018]2019**  
**Notice of Continuation: January 5, 2015**

**Authorizing, and Implemented or Interpreted Law: 58-17b-101; 58-17b-601(1); 58-37-1; 58-1-106(1)(a); 58-1-202(1)(a)**

**Health, Disease Control and  
 Prevention, Health Promotion  
 R384-415  
 Electronic-Cigarette Substance  
 Standards**

**NOTICE OF PROPOSED RULE  
 (Amendment)  
 DAR FILE NO.: 44114  
 FILED: 10/01/2019**

**RULE ANALYSIS**

**PURPOSE OF THE RULE OR REASON FOR THE CHANGE:** Outdated dates in Sections R384-415-7 and R384-415-8 that reference requirements for tobacco retailers to comply with as of 08/08/2019 that need to align better with the FDA's changed timeline on regulating electronic cigarettes. When this rule was originally written, the FDA published timeline to approve electronic cigarette substance standards was planned to be on or before 08/08/2019. However the FDA's original timeline was delayed until August 2022 and then changed to May 2021 by court ruling. This timeline could change again. As a result, this administrative rule is out of date and should be updated so it no longer states a specific date in both Sections R384-415-7 and R384-415-8.

**SUMMARY OF THE RULE OR CHANGE:** In Section R384-415-7, the change modifies the date language and adds language that will better align with the FDA's electronic cigarette pre-market product process which has changed multiple times and is not a set date and eliminating the 08/08/2019 date from this administrative rule. In Section R384-415-8, the change modifies the date language for consistency in Subsection R384-415-8(1)(c) and instead adds language that will better align with the FDA's electronic cigarette pre-market product process which has changed multiple times and is not a set date and eliminating the 08/08/2019 date from this administrative rule.

**STATUTORY OR CONSTITUTIONAL AUTHORIZATION FOR THIS RULE:** Section 26-57-103

**ANTICIPATED COST OR SAVINGS TO:**  
 ♦ **THE STATE BUDGET:** These proposed rule changes are not expected to have any fiscal impact on the state budget because these changes do not affect the implementation of this rule; they simply clarify the process.  
 ♦ **LOCAL GOVERNMENTS:** These proposed rule changes are not expected to have any fiscal impact on local governments because these changes do not affect the implementation of this rule; they simply clarify the process.