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The information in this *Bulletin* is summarized in the *Utah State Digest (Digest)* of the same volume and issue number. The *Digest* is available by e-mail subscription or online. Visit https://rules.utah.gov/ for additional information.

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NOTICE OF SUBSTANTIVE CHANGE		
TYPE OF FILING: Amendment		
Rule or section number:	**R156-17b**	**Filing ID: 57204**

Agency Information

1. Title catchline:	Commerce, Professional Licensing	
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Please address questions regarding information on this notice to the persons listed above.		

General Information

2. Rule or section catchline:	
R156-17b. Pharmacy Practice Act Rule	
3. Are any changes in this filing because of state legislative action?	Changes are because of legislative action.
If yes, any bill number and session:	HB 475 (2024) and SB 207 (2024),
4. Purpose of the new rule or reason for the change:	
This amendment addresses rule amendments required by legislative changes made during the 2024 legislative session and other recommendations of the Utah Board of Pharmacy.	
5. Summary of the new rule or change:	
This proposed amendment makes the following changes to the Pharmacy Practice Act Rule. **2024 HB 475: School Prescription Amendments.** 2024 HB 475 modified provisions of the Utah Code related to the use and distribution of epinephrine and albuterol in schools. These medications are used as emergency treatments of acute allergic reactions and asthma symptoms respectively. 2024 HB 475 authorized the Utah Department of Health and Human Services to issue standing orders for prescriptions of these medications to be filled and distributed to schools throughout Utah and held as emergency supplies within the school. Under 2024 HB 475, the Division is required to make rules relating to these standing orders. The proposed rule change is made in accordance with that requirement in Section R156-17b-1005. **2024 SB 207: Repeal of Unprofessional Conduct for Failing to Identify Licensure Classification.** 2024 SB 207 repealed Utah Code Subsection 58-17b-603(2). This subsection deemed it unprofessional conduct for pharmacy employees to not identify themselves by licensure classification "when communicating by any means." Because of this repeal, the proposed changes removes references to this conduct in Section R156-17b-402 and Table 402. **Subsections R156-17b-102(23) and R156-17b-617g(1): Drug Supply Chain Security Amendments.** The proposed amendment eliminates several state-specific supply chain requirements and adopts in full the Federal requirements of Section 360eee of Title 21 of the United States Code, the Drug Supply Chain Security Act (DSCSA).	

Section R156-17b-303a: Removal of References to Pharmacy Technicians University. Under Utah Code Subsection 58-17b 305(1)(e), applicants for licensure as pharmacy technicians must complete a program of education and training meeting the standards established by Division rule. Currently, Section R156-17b-303a requires this training to be conducted by "Pharmacy Technicians University or a branch of the Armed Forces of the United States." The Utah Pharmacy Board voted to remove references to the Pharmacy Technicians University during its November 19, 2024 meeting to allow any program the Division approves after review and consultation with the Utah Pharmacy Board to conduct the required training of pharmacy technicians. The Division agrees with the Board's findings.

Section R156-17b-303a: Timing of Application for Pharmacy Intern Licenses. The proposed amendment clarifies that an applicant seeking a pharmacy intern license may apply either (i) after becoming actively enrolled in a pharmacy program, or (ii) after being accepted into a program, but no more than 90 days prior to the applicant's enrollment in that pharmacy program.

Section R156-17b-303c: Qualifications for Licensure as Pharmacists. The proposed amendment clarifies the qualifications required for pharmacist and licenses in two ways: (1) Which exams are required for licensure based on the type of application and (2) how many attempts an applicant may be allowed to pass any exam before the applicant must repeat their educational requirements.

The proposed rule change clarifies that traditional applicants, who were previously unlicensed, must pass the NAPLEX and Utah Multistate Pharmacy Jurisprudence Examination (Utah MPJE) within five years after completing their course of study. Alternatively, because the NAPLEX is required by all other states, an applicant already licensed in another state and seeking licensure in Utah by endorsement need only take the Utah MPJE.

Additionally, the proposed amendment sets limits on the number of attempts an applicant may have to pass the NAPLEX or Utah MPJE. These changes will bring the rule into alignment with current Board standards. Applicants who fail any required examination three times will continue to need Board approval prior to any further attempt, failing any examination five times requires the applicant to complete another education program in accordance with Utah Code Subsection 58-17b-303(1)(e) before an additional authorization to test.

Section R156-17b-308: Reinstatement of Expired Pharmacist and Pharmacy Technician Licenses. The proposed rule change makes changes to the process by which pharmacists and pharmacy technicians whose license was active and in good standing at the time of expiration may apply for reinstatement. Licensees in good standing at the time of expiration will continue to renewing their licenses under Subsections R156-1-308g(1) and (2). Licensees whose licenses expired between two years and five years of the application for reinstatement will not be granted unless the applicant provides documentation of completion of all continuing education requirements that would otherwise have been required as though the license had never expired.

Applicants seeking restatement after five years must retake the exams listed in Section R156-17b-303c.

Section R156-17b-309: Continuing Education Requirements. As a condition of licensure, pharmacists must complete 30 hours continuing education during each two-year licensing period. Currently, Subsection R156-17b-309(1)(b) requires that 15 of these hours must be in disease state management therapy, AIDS therapy, patient safety, or immunization. The proposed rule change removes these specified topics but requires all credit hours be relevant to the licensee's professional practice.

Section R156-17b-402: Table 402 - Fine Schedule. The fine schedule was reformatted and updated to bring Table 402 into harmony with Title 58, Chapter 17b, the Pharmacy Practice Act. Additionally, after discussion with the Utah Pharmacy Board, the table was updated to include guidance for two violations of the Pharmacy Practice Act that were not listed: (1) Violations of Utah Code Subsection 58-1-501(1)(g) which prohibits as unlawful conduct licensees from aiding and abetting others to violate any statute, rule, or order relating to Title 58, and (2) violations of Utah Code Subsection 58-1-501(2)(a)(xv) which prohibits as unprofessional conduct any licensee from violating an order governing a license regulated under Title 58.

Section R156-17b-614e: Changes in Hazardous Drug Compounding Safety and Production Standards. Under Utah Code Section 58-1-203 and Section R156-17b-203, DOPL created the Advisory Pharmacy Compounding Education Committee (the Compounding Committee) to review and make recommendations to the Division and the Board on issues specifically related to the practice of pharmacy compounding. After review of current federal rules and industry standards set forth in the United States Pharmacopeia (USP), the Compounding Committee recommended that the Division amend the current rules to more clearly align with current standards relating to compounded medications listed on the National Institute for Occupational Safety and Health's (NIOSH) list of Hazardous Drugs in Healthcare Settings. These USP standards for the compounding of medications on the NIOSH list have been in effect for several years, have been adopted in whole or in part in several states, and are deferred to by other administrative agencies such as the Federal Occupational Safety and Health Administration. The development of the proposed rule for Utah's hazardous drug compounding pharmacies required several meetings of the Compounding Committee and the Board. After these deliberations, the Board reviewed the Committee's final proposal and recommended its adoption during the November 19, 2024 meeting.

Section R156-17b-623: Approved Cosmetic Drugs and Injectable Weight Loss Drugs for Dispensing Medical Practitioners. Currently, Section R156-17b-623, allows dispensing medical practitioners to administer legend, non-controlled drugs approved under the Online Prescribing, Dispending, and Facilitation Licensing Act and its accompanying rule. This act, however, was repealed in 2023 by Senate Bill 123 (2023 Utah Laws 249). The proposed rule change therefore removes reference to the repealed statute and rule and instead lists the following legend, non-controlled drugs: (a) hormonal-based contraception (except injectable or implantable methods), (b) hydroquinone up to 4%, and (c) tretinoin up to 0.1%.

Updating Internal References. The proposed amendment corrects and updates various internal references within the Pharmacy Practice Act Rule to reflect the current referencing in statute and rule.

Fiscal Information

6. Provide an estimate and written explanation of the aggregate anticipated cost or savings to:

A. State budget:

2024 HB 475: School Prescription Amendments. The proposed amendment reflects changes required by new legislation. All costs relating to legislation (including the costs or savings of implementing necessary rule changes) are part of the fiscal notes to that legislation. The proposed changes to the rule, consequently, have no further fiscal impact to the State budget than was disclosed in the legislation's fiscal notes.

2024 SB 207: Repeal of Unprofessional Conduct for Failing to Identify Licensure Classification. The proposed amendment reflects changes required by new legislation. All costs relating to legislation (including the costs or savings of implementing necessary rule changes) are part of the fiscal notes to that legislation. The proposed changes to the rule, consequently, have no further fiscal impact to the State budget than was disclosed in the legislation's fiscal notes.

Subsections R156-17b-102(23) and R156-17b-617g(1): Drug Supply Chain Security Amendments. The proposed amendment brings Utah drug supply chain regulation in line with Federal regulations by removing redundancies between the state and federal rules. This change is not anticipated to impact to the State Budget.

Section R156-17b-303a: Removal of References to Pharmacy Technicians University. The proposed amendment vests the Division with the power to determine the adequacy of a proposed pharmacy technicians training programs. The duties associated with this process are already part of the job description of personnel within the Division. It is not anticipated that additional resources from the state budget will need to be tasked to enact the proposed amendment.

Section R156-17b-303a: Timing of Application for Pharmacy Intern Licenses. The proposed amendment clarifies longstanding policy that a pharmacy intern must be enrolled in an education program to qualify for pharmacy intern licensing and is not expected to impact the state budget.

Section R156-17b-303c: Qualifications for Licensure as Pharmacists. The proposed amendment clarifies when and if certain examinations must be taken by applicants for a pharmacist license. The state budget will not be impacted by this change.

Section R156-17b-308: Reinstatement of Expired Pharmacist and Pharmacy Technician Licenses. The proposed amendment clarifies the procedures for the reinstatement of licenses when the license was active and in good standing at the time of expiration. The state budget will not be impacted by this change.

Section R156-17b-309: Continuing Education Requirements. The proposed amendment simplifies the required curriculum for licensees' continuing education. The state budget will not be impacted by this change.

Section R156-17b-501: Table 402 - Fine Schedule. The proposed amendment makes conforming changes to referencing changes in the Pharmacy Practice Act but makes no substantive change. In addition to these conforming changes, references were added that recommend fines for violations of Utah Code Subsections 58-1-501(1)(g) and 58-1-501(2)(a)(xv). These changes do not create new obligations under the law, but merely reflect the current range licensees who violate those terms may expect to pay. Consequently, none of the changes to Table 402 will impact the state budget.

Section R156-17b-614e: Changes in Hazardous Drug Compounding Safety and Production Standards. The proposed amendment updates the rule to reflect current industry standards regarding Hazardous Drug Compounding Safety and Production. The Division currently regulates these practices. It is anticipated that updating training materials and policies by the Division will cost approximately $1,000 in the first year with *de minimis* on-going costs to the state budget in subsequent years.

Section R156-17b-623: Approved Cosmetic Drugs and Injectable Weight Loss Drugs for Dispensing Medical Practitioners. The proposed amendment removes reference to statutes and rules that have been repealed and inserts the substance of those rules directly into the Pharmacy Practice Act Rule. None of the rights and responsibilities of the stakeholders will be impacted by this change and, therefore, it is not anticipated to have an impact on the state budget.

Updating Internal References. The proposed amendment updates several references to provisions of law and rule but makes no substantive change to the roles or responsibilities of stakeholders. These changes are not expected to have an impact to the state budget.

B. Local governments:

2024 HB 475: School Prescription Amendments. The proposed amendment reflects changes required by new legislation. All costs relating to legislation (including the costs or savings of implementing necessary rule changes) are part of the fiscal notes to that legislation. The proposed changes to the rule, consequently, have no further fiscal impact to local government than was disclosed in the legislation's fiscal notes.

2024 SB 207: Repeal of Unprofessional Conduct for Failing to Identify Licensure Classification. The proposed amendment reflects changes required by new legislation. All costs relating to legislation (including the costs or savings of implementing necessary rule changes) are part of the fiscal notes to that legislation. The proposed changes to the rule, consequently, have no further fiscal impact to local government than was disclosed in the legislation's fiscal notes.

Subsections R156-17b-102(23) and R156-17b-617g(1): Drug Supply Chain Security Amendments. The proposed amendment brings Utah drug supply chain regulation in line with Federal regulations by removing redundancies between the state and federal rules. This change is not anticipated to impact local governments.

Section R156-17b-303a: Removal of References to Pharmacy Technicians University. The proposed amendment vests the Division with the power to determine the adequacy of a proposed pharmacy technicians training programs. These duties are solely within the Division and not anticipated to impact local governments.

Section R156-17b-303a: Timing of Application for Pharmacy Intern Licenses. The proposed amendment clarifies longstanding policy that pharmacy intern must be enrolled in an education program to qualify for pharmacy intern licensing and is not expected to impact local governments.

Section R156-17b-303c: Qualifications for Licensure as Pharmacists. The proposed amendment clarifies when and if certain examinations must be taken by applicants for a pharmacist license. Local governments will not be impacted by this change.

Section R156-17b-308: Reinstatement of Expired Pharmacist and Pharmacy Technician Licenses. The proposed amendment clarifies the procedures for the reinstatement of licenses when the license was active and in good standing at the time of expiration. Local governments will not be impacted by this change.

Section R156-17b-309: Continuing Education Requirements. The proposed amendment simplifies the required curriculum for licensees' continuing education. Local governments will not be impacted by this change.

Section R156-17b-501: Table 402 - Fine Schedule. The proposed amendment makes conforming changes to referencing changes in the Pharmacy Practice Act but makes no substantive change. In addition to these conforming changes, references were added that recommend fines for violations of Utah Code Subsections 58-1-501(1)(g) and 58-1-501(2)(a)(xv). These changes do not create new obligations under the law, but merely reflect the current range licensees who violate those terms may expect to pay. Consequently, none of the changes to Table 402 will impact the budgets of local governments.

Section R156-17b-614e: Changes in Hazardous Drug Compounding Safety and Production Standards. The proposed amendment updates the rule to reflect current industry standards regarding Hazardous Drug Compounding Safety and Production. Some facilities that currently engage in hazardous drug compounding may require retro-fitting or remediation of their current facilities to meet these new standards that could, conceivably require construction permitting and associated inspections typically overseen by local governments. These costs, however, will be entirely offset by permit-related fees charged by the local governments.

Section R156-17b-623: Approved Cosmetic Drugs and Injectable Weight Loss Drugs for Dispensing Medical Practitioners. The proposed amendment removes reference to statutes and rules that have been repealed and inserts the substance of those rules directly into the Pharmacy Practice Act Rule. None of the rights and responsibilities of the stakeholders will be impacted by this change and, therefore, it is not anticipated to have an impact on local governments.

Updating Internal References. The proposed amendment updates several references to provisions of law and rule but makes no substantive change to the roles or responsibilities of stakeholders. These changes are not expected to have an impact on local governments.

C. Small businesses ("small business" means a business employing 1-49 persons)**:**

2024 HB 475: School Prescription Amendments. The proposed amendment reflects changes required by new legislation. All costs relating to legislation (including the costs or savings of implementing necessary rule changes) are part of the fiscal notes to that legislation. The proposed changes to the rule, consequently, have no further fiscal impact on small businesses than was disclosed in the legislation's fiscal notes.

2024 SB 207: Repeal of Unprofessional Conduct for Failing to Identify Licensure Classification. The proposed amendment reflects changes required by new legislation. All costs relating to legislation (including the costs or savings of implementing necessary rule changes) are part of the fiscal notes to that legislation. The proposed changes to the rule, consequently, have no further fiscal impact on small businesses than was disclosed in the legislation's fiscal notes.

Subsections R156-17b-102(23) and R156-17b-617g(1): Drug Supply Chain Security Amendments. The proposed amendment brings Utah drug supply chain regulation in line with Federal regulations by removing redundancies between the state and federal rules. This change reduces the complexity of compliance costs from businesses engaged in the drug supply change thereby saving small businesses up to $1,000 per year in simplified compliance costs.

Section R156-17b-303a: Removal of References to Pharmacy Technicians University. The proposed amendment removes Pharmacy Technicians University as a named pharmacy technician training program and vests in the Division (after consultation with the Utah Board of Pharmacy) the power to determine the adequacy of proposed pharmacy technicians training programs. Small businesses that provide pharmacy technician training programs, will no longer be able to use the Pharmacy Technicians University to train new pharmacy technicians, however, no small business is required by the proposed rule to incur the costs of creating these programs. Consequently, the Division does not anticipate any mandatory costs or material economic impacts to small businesses.

Section R156-17b-303a: Timing of Application for Pharmacy Intern Licenses. The proposed amendment clarifies the longstanding policy that a pharmacy intern must be enrolled in an education program to qualify for pharmacy intern licensing and is not expected to impact on any small business currently employing properly qualified pharmacy interns.

Section R156-17b-303c: Qualifications for Licensure as Pharmacists. The proposed amendment clarifies when and if certain examinations must be taken by applicants for a pharmacist license. Small businesses will not be impacted by this change.

Section R156-17b-308: Reinstatement of Expired Pharmacist and Pharmacy Technician Licenses. The proposed amendment clarifies the procedures for the reinstatement of licenses when the license was active and in good standing at the time of expiration. Small businesses will not be impacted by this change.

Section R156-17b-309: Continuing Education Requirements. The proposed amendment simplifies the required curriculum for licensees' continuing education. Small businesses will not be impacted by this change.

Section R156-17b-501: Table 402 - Fine Schedule. The proposed amendment makes conforming changes to referencing changes in the Pharmacy Practice Act but makes no substantive change. In addition to these conforming changes, references were added that recommend fines for violations of Utah Code Subsections 58-1-501(1)(g) and 58-1-501(2)(a)(xv). These changes do not create new obligations under the law, but merely reflect the current range licensees who violate those terms may expect to pay. Consequently, none of the changes to Table 402 will impact small businesses.

Section R156-17b-614e: Changes in Hazardous Drug Compounding Safety and Production Standards. The proposed amendment updates the rule to reflect current industry standards regarding Hazardous Drug Compounding Safety and Production based on current guidelines in the United States Pharmacopeia (USP). The Division believes these costs will vary depending on the nature of the compounding business. The most rigorous safety standards proposed in this rule are directed at facilities compounding category 1 substances (as defined by the National Institute for Occupational Safety and Health's (NIOSH) list of Hazardous Drugs in Healthcare Settings). This type of compounding is not typically undertaken by small businesses. Moreover, during their analysis, review, and deliberation (which included substantial input from stakeholders) the Advisory Pharmacy Compounding Education Committee (the Compounding Committee) and the Board determined that most small businesses engaged in the compounding of hazardous drugs currently meet, or are substantially close to meeting, current USP standards. Small businesses that currently do not meet the standards set forth in the proposed amendment may be required to purchase new equipment, retrofit existing workspaces, and retrain personnel. The Division believes these costs will generally be less than $5,000 in one-time costs for small businesses with only limited costs going forward.

Section R156-17b-623: Approved Cosmetic Drugs and Injectable Weight Loss Drugs for Dispensing Medical Practitioners. The proposed amendment removes reference to statutes and rules that have been repealed and inserts the substance of those rules directly into the Pharmacy Practice Act Rule. None of the rights and responsibilities of the stakeholders will be impacted by this change and, therefore, it is not anticipated to have an impact on any small business.

Updating Internal References. The proposed amendment updates several references to provisions of law and rule but makes no substantive change to the roles or responsibilities of stakeholders. These changes are not expected to have an impact on any small business.

D. Non-small businesses ("non-small business" means a business employing 50 or more persons)**:**

2024 HB 475: School Prescription Amendments. The proposed amendment to this rule arises from legislative changes made during the 2024 legislative session. All costs relating to those changes (including the costs or savings of implementing the rule changes proposed here) were included in the fiscal notes to that legislation. This rule change, therefore, will not have any anticipated fiscal impact on non-small businesses beyond what was stated in those fiscal notes.

2024 SB 207: Repeal of Unprofessional Conduct for Failing to Identify Licensure Classification. The proposed amendment to this rule arises from legislative changes made during the 2024 legislative session. All costs relating to those changes (including the costs or savings of implementing the rule changes proposed here) were included in the fiscal notes to that legislation. This rule change, therefore, will not have any anticipated fiscal impact on non-small businesses beyond what was stated in those fiscal notes.

Subsections R156-17b-102(23) and R156-17b-617g(1): Drug Supply Chain Security Amendments. The proposed amendment brings Utah drug supply chain regulation in line with Federal regulations by removing redundancies between the state and federal rules. This change is intended to simplify compliance from non-small businesses engaged in the drug supply change thereby saving non-small businesses up to $1,000 per year in compliance costs.

Section R156-17b-303a: Removal of References to Pharmacy Technicians University. The proposed amendment removes Pharmacy Technicians University as a named pharmacy technician training program and vests in the Division (after consultation with the Utah Board of Pharmacy) the power to determine the adequacy of any proposed pharmacy technicians training program. Non-Small businesses that provide pharmacy technician training programs will no longer be able to use Pharmacy Technicians University to train new pharmacy technicians, however, no non-small business is required by the proposed rule to incur the costs of creating alternative programs. Consequently, the Division does not anticipate any mandatory costs or material economic impacts to non-small businesses.

Section R156-17b-303a: Timing of Application for Pharmacy Intern Licenses. The proposed amendment clarifies longstanding policy that a pharmacy intern must be enrolled in an education program to qualify for pharmacy intern licensing and is not expected to impact non-small businesses.

Section R156-17b-303c: Qualifications for Licensure as Pharmacists. The proposed amendment clarifies when and if certain examinations must be taken by applicants for a pharmacist license. Non-small businesses will not be impacted by this change.

Section R156-17b-308: Reinstatement of Expired Pharmacist and Pharmacy Technician Licenses. The proposed amendment clarifies the procedures for the reinstatement of licenses when the license was active and in good standing at the time of expiration. Non-small businesses will not be impacted by this change.

Section R156-17b-309: Continuing Education Requirements. The proposed amendment simplifies the required curriculum for licensees' continuing education. Non-small businesses will not impacted by this amendment.

Section R156-17b-501: Table 402 - Fine Schedule. The proposed amendment makes conforming changes to referencing changes in the Pharmacy Practice Act but makes no substantive change. In addition to these conforming changes, references were added that recommend fines for violations of Utah Code Subsections 58-1-501(1)(g) and 58-1-501(2)(a)(xv). These changes do not create new obligations under the law, but merely reflect the current range licensees who violate those terms may expect to pay. Consequently, none of the changes to Table 402 will impact non-small businesses.

R156-17b-614e: Changes in Hazardous Drug Compounding Safety and Production Standards. The proposed amendment updates the rule to reflect current industry standards regarding Hazardous Drug Compounding Safety and Production based on current guidelines found in the United States Pharmacopeia (USP). The Division believes these costs will vary depending on the nature of the compounding in which a non-small business is engaged.

In determining the fiscal impact of the proposed rule to non-small businesses, the Division notes that the standards proposed have been considered part of the industry standard for hazardous drug compounding for years and have been considered by the Advisory Pharmacy Compounding Education Committee (the Compounding Committee) and the Board since 2020. While not yet formalized into a rule by the Division, the USP safety standards are relied upon by the Occupational Health and Safety Administration (OSHA) and other labor agencies in determining matters of worker and public safety. Consequently, many non-small businesses have already substantially adopted the USP guidelines.

During its March 25, 2025 public meeting, the Board advised, and the Division agrees, that for purposes of this fiscal impact analysis, non-small businesses engaged in hazardous drug compounding can be divided into two groups: Those that compound using category 1 substances (as defined by the National Institute for Occupational Safety and Health's (NIOSH) list of Hazardous Drugs in Healthcare Settings), and those that do not engage in the compounding of category 1 substances. There are very few non-small businesses engaged in category 1 hazardous drug compounding in Utah. The Division believes these entities have, almost universally, already adopted the USP standards as part of their business practices due to concerns regarding worker and public safety as well as engagement with the Compounding Committee and the Board.

Non-category 1 hazardous drug compounders do not share the same degree of safety and health standards as their category 1 counterparts. Consequently, the costs associated with compliance are substantially less than their category 1 counterparts and may include the purchase of new equipment, retrofitting of existing workspaces, and retraining personnel on a limited basis.

Given that substantial compliance already present in both category 1 and non-category 1 non-small business compounding facilities, the Division believes total one-time compliance costs will not exceed $10,000 for non-small businesses requiring remediation with only very limited increased operating costs on an ongoing basis.

Section R156-17b-623: Approved Cosmetic Drugs and Injectable Weight Loss Drugs for Dispensing Medical Practitioners. The proposed amendment removes reference to statutes and rules that have been repealed and inserts the substance of those rules directly into the Pharmacy Practice Act Rule. None of the rights and responsibilities of the stakeholders will be impacted by this change and, therefore, it is not anticipated to have an impact on non-small businesses.

Updating Internal References. The proposed amendment updates several references to provisions of law and rule but makes no substantive change to the roles or responsibilities of stakeholders. These changes are not expected to have an impact on non-small businesses.

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

2024 HB 475: School Prescription Amendments. The proposed amendment reflects changes required by new legislation. All costs relating to legislation (including the costs or savings of implementing necessary rule changes) are part of the fiscal notes to that legislation. The proposed changes to the rule, consequently, have no fiscal impact on persons other than small businesses, non-small businesses, state, or local government entities beyond those impacts disclosed in the legislation's fiscal notes.

2024 SB 207: Repeal of Unprofessional Conduct for Failing to Identify Licensure Classification. The proposed amendment reflects changes required by new legislation. All costs relating to legislation (including the costs or savings of implementing necessary rule changes) are part of the fiscal notes to that legislation. The proposed changes to the rule, consequently, have no fiscal impact on persons other than small businesses, non-small businesses, state, or local government entities beyond those impacts disclosed in the legislation's fiscal notes.

Subsections R156-17b-102(23) and R156-17b-617g(1): Drug Supply Chain Security Amendments. The proposed amendment brings Utah drug supply chain regulation in line with Federal regulations by removing redundancies between the state and federal rules. This change is not anticipated to impact persons other than small businesses, non-small businesses, state, or local government entities.

Section R156-17b-303a: Removal of References to Pharmacy Technicians University. The proposed amendment removes Pharmacy Technicians University as a named pharmacy technician training program and vests in the Division (after consultation with the Utah Board of Pharmacy) the power to determine the adequacy of proposed pharmacy technicians training programs. Persons other than small businesses, non-small businesses, state, or local government entities will likely see a drop in the program tuition by $200 as competition increases within the market.

Section R156-17b-303a: Timing of Application for Pharmacy Intern Licenses. The proposed amendment clarifies the longstanding policy that a pharmacy intern must be enrolled in an education program to qualify for pharmacy intern licensing and is not expected to impact persons other than small businesses, non-small businesses, state, or local government entities.

Section R156-17b-303c: Qualifications for Licensure as Pharmacists. The proposed amendment clarifies when and if certain examinations must be taken by applicants for a pharmacist license. This will not have a fiscal impact on persons other than small businesses, non-small businesses, state, or local government entities.

Section R156-17b-308: Reinstatement of Expired Pharmacist and Pharmacy Technician Licenses. The proposed amendment clarifies the procedures for the reinstatement of licenses when the license was active and in good standing at the time of expiration. This will not have a fiscal on impact persons other than small businesses, non-small businesses, state, or local government entities.

Section R156-17b-309: Continuing Education Requirements. The proposed amendment simplifies the required curriculum for licensees' continuing education. This will not have a fiscal impact on persons other than small businesses, non-small businesses, state, or local government entities.

Section R156-17b-501: Table 402 - Fine Schedule. The proposed amendment makes conforming changes to referencing changes in the Pharmacy Practice Act but makes no substantive change. In addition to these conforming changes, references were added that recommend fines for violations of Utah Code Subsections 58-1-501(1)(g) and 58-1-501(2)(a)(xv). These changes do not create new obligations under the law, but merely reflect the current range licensees who violate those terms may expect to pay. Consequently, none of the changes to Table 402 will impact persons other than small businesses, non-small businesses, state, or local government entities.

Section R156-17b-614e: Changes in Hazardous Drug Compounding Safety and Production Standards. The proposed amendment updates the rule to reflect current industry standards regarding Hazardous Drug Compounding Safety and Production. This sort of compounding is not likely to be performed by persons other than small businesses, non-small businesses, state, or local government entities. The Division anticipates no fiscal impact to persons other than small businesses, non-small businesses, state, or local government entities a small business.

Section R156-17b-623: Approved Cosmetic Drugs and Injectable Weight Loss Drugs for Dispensing Medical Practitioners. The proposed amendment removes reference to statutes and rules that have been repealed and inserts the substance of those rules directly into the Pharmacy Practice Act Rule. None of the rights and responsibilities of the stakeholders will be impacted by this change and, therefore, it is not anticipated to have a fiscal impact on persons other than small businesses, non-small businesses, state, or local government entities a small business.

Updating Internal References. The proposed amendment updates several references to provisions of law and rule but makes no substantive change to the roles or responsibilities of stakeholders. These changes are not expected to have a fiscal impact on persons other than small businesses, non-small businesses, state, or local government entities a small business.

F. Compliance costs for affected persons:

2024 HB 475: School Prescription Amendments. The proposed amendment reflects changes required by new legislation. All costs relating to legislation (including the costs or savings of implementing necessary rule changes) are part of the fiscal notes to that legislation. The proposed changes to the rule, consequently, have no further fiscal impact on any affected person than was disclosed in the legislation's fiscal notes.

2024 SB 207: Repeal of Unprofessional Conduct for Failing to Identify Licensure Classification. The proposed amendment reflects changes required by new legislation. All costs relating to legislation (including the costs or savings of implementing necessary rule changes) are part of the fiscal notes to that legislation. The proposed changes to the rule, consequently, have no further fiscal impact on any affected person than was disclosed in the legislation's fiscal notes.

Subsections R156-17b-102(23) and R156-17b-617g(1): Drug Supply Chain Security Amendments. The proposed amendment brings Utah drug supply chain regulation in line with Federal regulations by removing redundancies between the state and federal rules. This change is intended to simplify compliance from businesses engaged in the drug supply change thereby saving affected persons up to $500 per year in compliance costs.

Section R156-17b-303a: Removal of References to Pharmacy Technicians University. The proposed amendment vests the Division with the power to determine the adequacy of a proposed pharmacy technicians training programs. Affected individuals (those seeking training as pharmacy technicians) will more likely experience a decrease rather than increase in costs.

Section R156-17b-303a: Timing of Application for Pharmacy Intern Licenses. The proposed amendment clarifies longstanding policy that pharmacy intern must be enrolled in an education program to qualify for pharmacy intern licensing and is not expected to have any fiscal impact on affected persons.

Section R156-17b-303c: Qualifications for Licensure as Pharmacists. The proposed amendment clarifies when and if certain examinations must be taken by applicants for a pharmacist license. Affected persons will not be impacted by the amendments fiscally as the proposed amendment only clarifies current policies within the Division and the Utah Board of Pharmacy.

Section R156-17b-308: Reinstatement of Expired Pharmacist and Pharmacy Technician Licenses. The proposed amendment clarifies the procedures for the reinstatement of licenses when the license was active and in good standing at the time of expiration. Affected persons will not be fiscally impacted by this change.

Section R156-17b-309: Continuing Education Requirements. The proposed amendment simplifies the required curriculum for licensees' continuing education. Affected persons will not be fiscally impacted by this change.

Section R156-17b-501: Table 402 - Fine Schedule. The proposed amendment makes conforming changes to referencing changes in the Pharmacy Practice Act but makes no substantive change. In addition to these conforming changes, references were added that recommend fines for violations of Utah Code Subsections 58-1-501(1)(g) and 58-1-501(2)(a)(xv). These changes do not create new obligations under the law, but merely reflect the current range licensees who violate those terms may expect to pay. Consequently, none of the changes to Table 402 will impact affected persons.

Section R156-17b-614e: Changes in Hazardous Drug Compounding Safety and Production Standards. The proposed amendment updates the rule to reflect current industry standards regarding Hazardous Drug Compounding Safety and Production. In determining the fiscal impact of the proposed rule on affected persons, the Division notes that the proposed amendments have been considered part of the industry standard for hazardous drug compounding for years and have been considered by the Advisory Pharmacy Compounding Education Committee (the Compounding Committee) and the Board since 2020. While not yet formalized into a rule by the Division, the USP safety standards are relied upon by the Occupational Health and Safety Administration (OSHA) and other labor agencies in determining matters of worker and public safety. Consequently, the Division believes most affected persons have already substantially adopted the USP guidelines.

The Division therefore concludes that the initial compliance costs to affected persons will not exceed $10,000 with only very limited increased operating costs on an ongoing basis. Due to the highly hazardous nature of the substances used, affected persons compounding category 1 substances (as defined by the National Institute for Occupational Safety and Health's (NIOSH) list of Hazardous Drugs in Healthcare Settings), who are not already in compliance with USP safety standards, will likely fall on the higher end of this estimate. Conversely, affected persons engaging in non-category 1 compounding will likely incur fewer costs.

Section R156-17b-623: Approved Cosmetic Drugs and Injectable Weight Loss Drugs for Dispensing Medical Practitioners. The proposed amendment removes reference to statutes and rules that have been repealed and inserts the substance of those rules directly into the Pharmacy Practice Act Rule. None of the rights and responsibilities of affected persons be fiscally impacted by this change.

Updating Internal References. The proposed amendment updates several references to provisions of law and rule but makes no substantive change to the roles or responsibilities of stakeholders. These changes are not expected to have an impact on any person.

G. Regulatory Impact Summary Table (This table includes only fiscal impacts the agency was able to measure. If the agency could not estimate an impact, it is excluded from this table but described in boxes A through F.)

Regulatory Impact Summary Table					
Fiscal Cost	**FY2026**	**FY2027**	**FY2028**	**FY2029**	**FY2030**
State Budget	$1,000	$0	$0	$0	$0
Local Governments	$0	$0	$0	$0	$0
Small Businesses	$0	$0	$0	$0	$0
Non-Small Businesses	$5,000	$0	$0	$0	$0
Other Persons	$10,000	$0	$0	$0	$0
Total Fiscal Cost	**$16,000**	**$0**	**$0**	**$0**	**$0**
Fiscal Benefits	**FY2026**	**FY2027**	**FY2028**	**FY2029**	**FY2030**
State Budget	$0	$0	$0	$0	$0
Local Governments	$0	$0	$0	$0	$0
Small Businesses	$1,000	$1,000	$1,000	$1,000	$1,000

Non-Small Businesses	$1,000	$1,000	$1,000	$1,000	$1,000
Other Persons	$200	$200	$200	$200	$200
Total Fiscal Benefits	**$2,200**	**$2,200**	**$2,200**	**$2,200**	**$2,200**
Net Fiscal Benefits	**-$13,800**	**$2,200**	**$2,200**	**$2,200**	**$2,200**

H. Department head comments on fiscal impact and approval of regulatory impact analysis:

The Executive Director of the Department of Commerce, Margaret W. Busse, has reviewed and approved this regulatory impact analysis.

Citation Information

7. Provide citations to the statutory authority for the rule. If there is also a federal requirement for the rule, provide a citation to that requirement:

Section 63G-3-201	Subsection 58-1-106(1)(a)	Subsection 58-1-202(1)(a)
Section 58-17b-101	Subsection 58-17b-601(1)	Section 58-37-1

Incorporation by Reference Information

8. Incorporation by Reference :

A. This rule adds or updates the following title of material incorporated by reference (a copy of the material incorporated by reference must be submitted to the Office of Administrative Rules. *If none, leave blank*)**:**

Official Title of Materials Incorporated (from title page)	United States Pharmacopeia-National Formulary (USP 41-NF 36), including the First Supplement
Publisher	The United States Pharmacopeial Convention
Issue Date	USP 41-NF 36 was initially published November 1, 2017 The First Supplement was issued November 1, 2023.
Issue or Version	General Chapters <795>: Pharmaceutical Compounding – Nonsterile Preparations <797>: on Pharmaceutical Compounding – Sterile Preparations <800>: on Hazardous Drugs—Handling in Healthcare Settings <825>: on Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging

B. This rule adds or updates the following title of material incorporated by reference (a copy of the material incorporated by reference must be submitted to the Office of Administrative Rules. *If none, leave blank*)**:**

Official Title of Materials Incorporated (from title page)	Vaccine Administration Protocol: Standing Order to Administer Immunizations and Emergency Medications
Publisher	Utah Department of Health and Human Services
Issue Date	September 1, 2023

C. This rule adds or updates the following title of material incorporated by reference (a copy of the material incorporated by reference must be submitted to the Office of Administrative Rules. *If none, leave blank*)**:**

Official Title of Materials Incorporated (from title page)	Utah Guidance for Self-Administered Hormonal Contraceptives
Publisher	Utah Department of Commerce, Division of Professional Licensing
Issue Date	September 28, 2021

D. This rule adds or updates the following title of material incorporated by reference (a copy of the material incorporated by reference must be submitted to the Office of Administrative Rules. *If none, leave blank*)**:**	
Official Title of Materials Incorporated (from title page)	Utah Hormonal Contraceptive Self-Screening Risk Assessment Questionnaire
Publisher	Utah Department of Commerce, Division of Professional Licensing
Issue Date	September 28, 2021

Public Notice Information

9. The public may submit written or oral comments to the agency identified in box 1.		
A. Comments will be accepted until:		07/31/2025
B. A public hearing (optional) will be held (The public may request a hearing by submitting a written request to the agency, as outlined in Section 63G-3-302 and Rule R15-1.)**:**		
Date:	**Time:**	**Place** (physical address or URL)**:**
07/03/2025	02:00 PM	Anchor Meeting: Heber M. Wells Building Room 402 160 East 300 South Salt Lake City UT 84111 Google Meet: https://meet.google.com/zat-cbzz-bzc Dial In: 931-313-1776 PIN: 402 142 612#

10. This rule change MAY become effective on:	08/07/2025
NOTE: The date above is the date the agency anticipates making the rule or its changes effective. It is NOT the effective date.	

Agency Authorization Information

Agency head or designee and title:	Mark Steinagel Division Director	**Date:**	03/28/2025

R156. Commerce, Professional Licensing.
R156-17b. Pharmacy Practice Act Rule.
R156-17b-102. Definitions.

[~~The following definitions supplement the statutory definitions~~]Terms used in this rule are defined in Title 58, Chapter 1, Division of Professional Licensing Act, and Title 58, Chapter 17b, Pharmacy Practice Act. In addition:

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

(a) accredited; or

(b) in candidate status.

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

(3) "Analytical laboratory":

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(c) arresting or slowing a disease process.

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

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

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

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

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

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

(i) are therapeutically inert; and

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

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

[~~(15) "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.~~]

[~~(16)~~](15) "Counterfeit prescription drug" has the meaning given to the term "counterfeit drug" in 21 USC 321(g)(2) as applied to prescription drugs.

[~~(17)~~](16) "Counterfeiting" means engaging in activities that create a counterfeit prescription drug.

[~~(18)~~](17) "Dispense," as defined in Subsection 58-17b-102(22), does not include transferring medications for a patient from a legally dispensed prescription for that particular patient into a daily or weekly drug container to facilitate the patient taking the correct medication.

[~~(19)~~](18) "Designated representative" or "DR" means an individual supervising the licensed facility in accordance with Subsections R156-17b-615(4) and (5).

[~~(20)~~](19) "Device" means a prescription device as defined in 21 CFR 801.109 (2021).

[~~(21)~~](20) "DMP" means a dispensing medical practitioner licensed under Title 58, Chapter 17b, Part 8, Dispensing Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy.

[~~(22)~~](21) "DMP designee" means an individual, acting under the direction of a DMP, who:

(a)(i) holds an active health care professional license under one of the following Title 58 chapters:

(A) Chapter 67, Utah Medical Practice Act;

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

(C) Chapter 70a, Utah Physician Assistant Act;

(D) Chapter 31b, Nurse Practice Act;

(E) Chapter 16a, Utah Optometry Practice Act;

(F) Chapter 44a, Nurse Midwife Practice Act; or

(G) Chapter 17b, Pharmacy Practice Act; or

(ii) is a medical assistant as defined in Subsection 58-67-102(14);

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

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

[~~(23)~~](22) "DMPIC" means a dispensing-medical-practitioner-in-charge licensed under Title 58, Chapter 17b, Part 8, Dispensing Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy who is designated by a dispensing medical practitioner clinic pharmacy to be responsible for activities of the pharmacy.

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

[~~(24) "Drop-shipment" means the sale of a prescription drug to a pharmaceutical wholesaler by:~~

~~(a)(i) a manufacturer or the manufacturer's:~~

~~(A) co-licensed product partner;~~
~~(B) third party logistics provider; or~~
~~(C) exclusive distributor; or~~
~~(ii) an authorized distributor of record that purchased the product directly from the manufacturer or an entity listed in Subsection (24)(a)(i);~~
~~(b)(i) the pharmaceutical wholesale distributor takes title to but not physical possession of the prescription drug;~~
~~(ii) the pharmaceutical wholesale distributor invoices the pharmacy, pharmacy warehouse, or other person authorized by law to dispense or administer the drug; and~~
~~(iii) the pharmacy, pharmacy warehouse, or other person authorized by law to dispense or administer the drug receives delivery of the prescription drug directly from an entity listed in Subsection (24)(a).~~]

[~~(25)~~](24) "Drug therapy management" means the review of a drug therapy regimen of a patient by one or more pharmacists evaluating and rendering advice to one or more practitioners regarding adjustment of the regimen.

[~~(26)~~](25) "Drugs," as used in this rule, means drugs or devices.

[~~(27)~~](26) "Durable medical equipment" or "DME" means equipment that:

(a) can withstand repeated use;

(b) is primarily and customarily used to serve a medical purpose;

(c) generally is not useful to a person in the absence of an illness or injury;

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

(e) may include devices and medical supplies.

[~~(28)~~](27) "Entities under common administrative control" means an entity holds the power, actual as well as legal, to influence the management, direction, or functioning of a business or organization.

[~~(29)~~](28) "Entities under common ownership" means entity assets are held indivisibly rather than in the names of individual members.

[~~(30)~~](29) "ExCPT" means the Exam for the Certification of Pharmacy Technicians.

[~~(31)~~](30) "FDA" means the United States Food and Drug Administration and any successor agency.

[~~(32)~~](31) "FDA-Approved" means that the federal Food, Drug, and Cosmetic Act, 21 USC 301 et seq. and regulations promulgated thereunder permit the subject drug or device to be lawfully manufactured, marketed, distributed, and sold.

[~~(33)~~](32) "High-risk, medium-risk, and low-risk drugs" refers to the risk level to a patient's health from compounding sterile preparations, as referred to in USP-NF Chapter 797.

[~~(34)~~](33) "Hospice facility pharmacy" means a pharmacy that supplies drugs to patients in a licensed healthcare facility for terminal patients.

[~~(35)~~](34) "Hospital clinic pharmacy" means a pharmacy that is located in an outpatient treatment area where a pharmacist or pharmacy intern is compounding, admixing, or dispensing prescription drugs, and where:

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

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

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

[~~(36)~~](35) "Legend drug" or "prescription drug" means a drug or device that has been determined to be unsafe for self-medication or one that bears or is required to bear the legend:

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

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

(c) "Rx only".

[~~(37)~~](36) "Long-term care facility" as used in Section 58-17b-610.7 means the same as defined in Section 58-31b-102.

[~~(38)~~](37) "Managerial control" means the ability, regardless of title, to directly manage the finances, strategic initiatives, and personnel of a pharmacy or pharmaceutical facility, including:

(a) taking on debt obligations;

(b) distributing profits;

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

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

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

[~~(39)~~](38) "Maintenance medications" means medications [~~the~~]that a patient takes on an ongoing basis.

[~~(40)(a) "Manufacturer's exclusive distributor" means an entity that:~~
~~(i) contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer; and~~
~~(ii) takes title to that manufacturer's prescription drug, but does not have general responsibility to direct the drug's sale or disposition.~~
~~(b) To be considered part of the normal distribution channel, a manufacturer's exclusive distributor shall be:~~
~~(i) licensed as a pharmaceutical wholesaler; and~~
~~(ii) an authorized distributor of record.~~]

[~~(41)~~](39) "Medical supplies" means items for medical use that are:

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

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

[~~(42)~~](40) "MPJE" means the Multistate Jurisprudence Examination.

[~~(43)~~](41) "NABP" means the National Association of Boards of Pharmacy.

[~~(44)~~](42) "NAPLEX" means North American Pharmacy Licensing Examination.

[~~(45)~~](43) "Non-drug or device handling central prescription processing pharmacy" means a central prescription processing pharmacy that does not engage in compounding, packaging, labeling, dispensing, or administering of drugs or devices.

[~~(46)~~](44) "Normal distribution channel" means a chain of custody for a prescription drug sent:

(a)(i) directly from the manufacturer;

(ii) by drop-shipment;

(iii) via intracompany transfer from the manufacturer; or

(iv) from the manufacturer's:

(A) co-licensed partner;

(B) third party logistics provider; or

(C) exclusive distributor;

(b) to:

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

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

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

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

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

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

[~~(47)~~](45) "Parenteral" means a method of drug delivery injected into body tissues but not via the gastrointestinal tract.

[~~(48)~~](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 (4[~~5~~]6)(a), one of the following facilities:

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

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

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

[~~(49)~~](47) "Pedigree" means a document or electronic file containing information that records each distribution of any given prescription drug.

[~~(50)~~](48) "Pharmacy facility" ~~-~~means the same as "Pharmaceutical facility" ~~-~~defined in Subsection 58-17b-102(46).

[~~(51)~~](49) "PIC," as used in this rule, means the pharmacist-in-charge.

[~~(52)~~](50) "Prepackaged" or "Prepackaging" means transferring a drug, manually or by use of an automated pharmacy system, from a manufacturer's or distributor's original container to another container before receiving a prescription drug order or for a patient's immediate need for dispensing by a pharmacy or practitioner authorized to dispense in the establishment where the prepackaging occurred.

[~~(53)~~](51) "Prescription files" means hard copy and electronic prescriptions that includes pharmacist or technician notes, or information written or attached that is pertinent to the prescription.

[~~(54)~~](52) "Professional entry degree," as used in Subsection 58-17b-303(1)(e), means the professional entry degree offered by the applicant's ACPE-accredited school or college of pharmacy in the applicant's year of graduation, either a baccalaureate in pharmacy (BSPharm) or a doctorate in pharmacy (PharmD).

[~~(55)~~](53) "PTCB" means the Pharmacy Technician Certification Board.

[~~(56)~~](54) "Qualified continuing education," as used in this rule, means continuing education that meets the standards set forth in Section R156-17b-309.

[~~(57)~~](55) "Qualifying Ownership Change" means any transaction or series of transactions that results in a change in the ownership and managerial control of a pharmaceutical facility, but does not include changes in ownership:

(a) caused by changes in stockholders in publicly listed corporations whose stock is publicly traded;

(b) that do not result in a change in managerial control, including changes in the type of corporate entity under which the pharmaceutical facility is held;

(c) constituting less than 50% of the total ownership of the pharmaceutical facility; or

(d) of a parent entity holding an equitable interest in a pharmaceutical facility as a subsidiary, if the equitable interest constitutes less than 50% of the total ownership interest of the pharmaceutical facility.

[~~(58)~~](56) "Refill" means to fill again.

[~~(59)~~](57) "Remote dispensing pharmacist-in-charge" or "RDPIC" means the PIC of a remote dispensing pharmacy. The RDPIC shall be the PIC of the remote dispensing pharmacy's supervising pharmacy.

[~~(60)~~](58) "Remote dispensing pharmacy" means a Class A or Class B pharmacy located in Utah that serves as the originating site where a patient receiving services through a telepharmacy system is physically located and the practice of telepharmacy occurs, pursuant to Section R156-17b-614g.

[~~(61)~~](59) "Repackage" means repackaging or otherwise changing the container, wrapper, or labeling to further the distribution of a prescription drug, excluding that completed by the pharmacist or DMP responsible for dispensing the product to a patient.

[~~(62)~~](60) "Research facility" means a facility where research takes place that has policies and procedures describing such research.

[~~(63)~~](61) "Responsible party" means the identity of the supervisor or director or the Class E pharmacy under Section R156-17b-617a.

[~~(64)~~](62) "Reverse [~~distributor~~]distributing" means a person or company that retrieves unusable or outdated drugs from a pharmacy by removing those drugs from stock and destroying them.

[~~(65)~~](63) "Self-administered hormonal contraceptive" means the same as defined in Subsection 26B-4-501(22).

[~~(66)~~](64) "Sterile products preparation facility" means any facility, or portion of the facility, that compounds sterile products using aseptic techniques.

[~~(67)~~](65) "Supervising pharmacy" means the Class A or Class B pharmacy responsible for overseeing the operation of a remote dispensing pharmacy, and whose PIC is the RDPIC for the remote dispensing pharmacy, pursuant to Section R156-17b-614g.

[~~(68)~~](66) "Supervisor" means a licensed pharmacist or DMP in good standing with the Division.

[~~(69)~~](67) "Telepharmacy system" means any telecommunication or information technology system, or combination of systems, that monitors the preparation and dispensing of prescription drugs and provides for related drug review and HIPAA-compliant patient counseling services.

[~~(70)~~](68) "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.

[~~(71)~~](69) "Unauthorized personnel" means a person not participating in the operational processes of the pharmacy who in some way would interrupt the natural flow of pharmaceutical care.

[~~(72)~~](70) "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.

[~~(73)~~](71) "Unprofessional conduct," as defined in Title 58, Chapter 1, Division of Professional Licensing Act, [~~and~~]Title 58, Chapter 17b, Pharmacy Practice Act, and Subsection 58-1-203(1)(e) is further defined in Section R156-1-501[~~Subsection 58-1-203(1)(e)~~] and Section R156-17b-502.

[~~(74) 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, which is incorporated by reference, is the self-screening risk assessment questionnaire approved by the Division pursuant to Section 26-64-106.~~]

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

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

[~~(75)~~](74) "USP[~~-NF~~]" means the United States Pharmacopeia-National Formulary (USP 41-NF 36), including the First Supplement, dated November 1, 2023. The following general chapters are incorporated by reference:[~~(USP 41-NF 36), either First Supplement, dated August 1, 2018, or Second Supplement, dated December 1, 2018, which is incorporated by reference~~].

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

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

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

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

[~~(76)~~](75) "Vaccine Administration Protocol" means the Vaccine Administration Protocol: Standing Order to Administer Immunizations and Emergency Medications, adopted [~~September 24, 2020,~~]September 1, 2023, by the Division in collaboration with the Board and [~~Utah Physicians Licensing Board~~]Medical Licensing Board, which is incorporated by reference.

[~~(77)~~](76) "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.

[~~(78)~~](77) "Wholesale distribution" means the same as 21 CFR 203.3(cc) (2021).

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

Under Section 58-17b-302, th[**e**]is section clarifies the classification of pharmacies[~~- is clarified as follows:~~].

(1) A Class A pharmacy includes retail operations located in Utah. 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. A Class B pharmacy 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;
(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 physically located and includes an out-of-state mail service pharmacy. A Class D pharmacy 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) The Division shall convert all pharmacy licenses to the appropriate classification as identified in Section 58-17b-302.~~]
[~~(7)~~](6)(a) 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.
(b) [~~However, the~~]The PIC or DMPIC:
[~~(a)~~](i) 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)~~](ii) may serve as an RDPIC.
[~~(8)~~](7) A PIC, RDPIC, or DMPIC shall comply with Section R156-17b-603.

R156-17b-303a. Qualifications for Licensure - Pharmacist, Pharmacy Intern, and Pharmacy Technician - Education Requirements.
(1) Under Subsections 58-17b-303(2) and 58-17b-304(6)(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.
(2) Under Subsection 58-17b-304(6), an applicant for a pharmacy intern license shall:
(a) be a current pharmacy student in a college of pharmacy accredited by the ACPE, as evidenced by written verification from a dean of the college;[~~ or~~]
(b) hold a graduate degree from a foreign pharmacy school and have received a certificate of equivalency from an approved credentialing agency under Subsection (1); or[~~.~~]
(c) have been accepted to a college of pharmacy accredited by the ACPE, as evidenced by a written acceptance letter from the college of pharmacy showing that the applicant is expected to begin coursework in the college of pharmacy no more than 90 days from the date of the application.
(3) Under Subsection 58-17b-305(1)(e), a pharmacy technician shall complete a training program that:
(a) is accredited by:
(i) ASHP; or
(ii) the Accrediting Bureau of Health Education Schools (ABHES); or
(b) is conducted by:
(i) [~~Pharmacy Technicians University~~]a program approved by the Division in collaboration with the Board; or
(ii) a branch of the Armed Forces of the United States; and
(c) meets the following standards:
(i) requires completion, while licensed as a pharmacy technician trainee, of at least 180 hours of directly supervised practical training in a licensed pharmacy by a licensed pharmacist in good standing; and
(ii) has written protocols and guidelines for the teaching pharmacist outlining the use 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 any act, task, and function performed by the pharmacy technician trainee.

(4) A pharmacy technician trainee shall complete a pharmacy technician training program and pass the required examination in Subsection R156-17b-303c(4) within two years after obtaining their pharmacy technician trainee license, unless otherwise approved by the Division in collaboration with the Board for good cause showing exceptional circumstances. An individual who fails to comply with this time frame shall repeat a pharmacy technician training program in its entirety if the individual pursues licensure as a pharmacy technician.

[~~(5)(a) A pharmacy technician training program is exempt from satisfying ASHP or ABHES accreditation for students enrolled on or before December 31, 2024.~~

~~(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 before December 31, 2025.~~]

(5)(a) A Division approved program or program in ASHP candidate status shall notify a student before 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.

[~~(c)~~](b) A Division approved program or program in ASHP candidate status that is denied accreditation shall immediately notify the Division, enrolled students, and student practice sites, of the denial.

(c) The notice required in Subsection (5)(b) 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 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[~~,~~] who does not meet the qualifications for licensure by endorsement in Subsection 58-1-302[~~(1)~~](2), meets the qualifications for licensure in Subsections 58-1-302[~~(2)~~](3), 58-17b-305(1)(e), and 58-17b-305(1)(f) if the applicant:

(a)(i) 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

(ii) has equivalent experience as approved by the Division in collaboration with the Board; and

(b) has current PTCB or ExCPT certification.

R156-17b-303c. Qualifications for Licensure - Pharmacist and Pharmacy Technician - Examinations.

(1) An applicant seeking licensure as a pharmacist [~~U~~]under Subsection 58-17b-303(1)[~~(g)~~], [~~the examinations that shall be passed by an applicant for licensure as a pharmacist are~~]shall pass the following examinations within five years of graduation from a pharmacy program described in Subsection 58-17b-303(1)(e):

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

(b) the Utah [~~Multistate Pharmacy Jurisprudence Examination(MPJE)~~]MPJE with a passing score established by NABP.

(2) An applicant seeking licensure as a pharmacist by endorsement under Subsection 58-17b-303(3), shall pass the Utah MPJE, with a passing score established by NABP.

[~~(2)(a) An individual who has failed either examination three times shall meet with the Board to request an additional authorization to test.~~]

[~~(b) The Division, in collaboration with the Board, may require additional training as a condition for approval of an authorization to retest.~~]

[~~(3) Under Subsection 58-17b-303(3)(i), an applicant for license by endorsement as a pharmacist shall pass the Utah MPJE.~~]

(3) An applicant under Subsection 58-17b-303(1) or Subsection 58-17b-303(3) who has failed a required examination three times and wishes to retake the exam shall:

(a) meet with the Board to request authorization to test up to two additional attempts; and

(b) complete any additional training the Board may require before any approved additional attempts.

(4) An applicant under Subsection 58-17b-303(1) or Subsection 58-17b-303(3) who has failed a required examination five times and who wishes to retake the exam shall complete another education program in accordance with Subsection 58-17b-303(1)(e) before an additional authorization to test.

(5) An applicant shall pass any required examination within five years of graduation from an education program in accordance with Subsection 58-17b-303(1)(e).

[~~(4)~~](6)(a) Under Subsection 58-17b-305(1)(f), an applicant for licensure as a pharmacy technician shall pass the PTCB or ExCPT with a passing score established by the certifying body.

(b) A PTCB or ExCPT certificate shall show a valid date and that the certification is active.

[~~(5)~~](7) In addition to any applicable examination requirements of Subsection 58-17b-303(1)(g) or Subsection 58-17b-303(3)(i), a[~~A~~] graduate of a foreign pharmacy school seeking licensure under Subsection 58-17b-303(2) shall obtain a passing score on the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination.

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

[~~In accordance with~~]This section establishes procedures required in 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 Subsections (3) and (4).

(3) A[~~n~~] pharmacist[~~applicant~~] whose license was active and in good standing before its expiration [~~at the time of expiration~~]may apply for reinstatement[~~ between two years and eight years after the date of expiration~~], under[~~in accordance with~~] the following practice re-entry requirements:

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

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

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

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

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

[~~(4)~~](5) The Division, in collaboration with the Board, may approve the extension of an intern license upon the request of the licensee, if the intern lacks the required number of internship hours for licensure.

R156-17b-309. Continuing Education.

[~~In accordance with~~]Under Section 58-17b-310 and Subsections 58-1-203(1)(g) and 58-1-308(3)(b), this section establishes the continuing education (CE) requirements for renewal or reinstatement of a pharmacist or pharmacy technician license for each two-year renewal cycle.[~~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[~~, that shall include at minimum~~]:

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

(b) be relevant to the licensee's professional practice;[~~15 hours in one or more of the following topics:~~

~~(i) disease state management-drug therapy;~~

~~(ii) AIDS therapy;~~

~~(iii) patient safety; or~~

~~(iv) immunizations;~~]

(c) include one hour of pharmacy law or ethics;

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

(e) if engaging in the administration of prescription drugs or devices under[~~as defined in~~] Section R156-17b-621 or R156-17b-625, include 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 26B, Chapter 4[~~62~~], Family Planning Access Act[~~as defined in~~] under Section R156-17b-621b, include 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;

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

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

(b) Current PTCB or ExCPT certification shall fulfill each CE requirements for a pharmacy technician, except for 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 each CE requirements as provided in Section R156-1-308d.

(4) CE credit shall be recognized as follows:

(a)(i) [~~O~~]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; and[~~.~~]

(ii) [~~T~~]these hours may count as "pharmacy law or ethics" hours;[~~.~~]

(b)(i) [~~T~~]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;[~~.~~]

(ii) [~~T~~]the licensee shall document the course's content and intended audience such as[~~ (e.g.,~~] pharmacists, pharmacy technicians, pharmacy interns, physicians, or nurses[~~).~~]; and

(iii) [~~P~~]public service programs, such as presentations to schoolchildren or service clubs, are not eligible for CE credit; and[~~.~~]

(c) CE credit 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~~]if 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 are ACPE accredited and are sponsored by the Utah Pharmacy Association, the Utah Society of Health-System Pharmacists, or other professional organization or association; or[~~and~~]

(v) for pharmacists, programs of certification by qualified individuals such as certified diabetes educator credentials, board certification, 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 CE that cannot be tracked by the licensee's NABP plan.

R156-17b-402. Administrative Penalties.

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

TABLE 402
FINE SCHEDULE

SUBSECTION	VIOLATION	FIRST OFFENSE	SUBSEQUENT OFFENSE
(1)	58-1-501(1)(a)	$ 500 - $ 2,000	$ 2,000 - $ 10,000
(2)	58-1-501(1)(b)	$ 500 - $ 2,000	$ 2,000 - $ 10,000
(3)	58-1-501(1)(c)	$ 500 - $ 1,000	$ 1,000 - $ 5,000
(4)	58-1-501(1)(d)	$ 500 - $ 1,000	$ 1,000 - $ 5,000
(5)	58-1-501(1)(e)	$ 100 - $ 2,000	$ 2,000 - $ 10,000
(6)	58-1-501(1)(f)(i)(A)	$ 500 - $ 2,000	$ 2,000 - $ 10,000
[~~(7)~~]	[~~58-1-501(2)(m)(i)~~]	[~~$ 500 - $ 2,000~~]	[~~$ 2,000 - $ 10,000~~]
[~~(8)~~]	[~~58-1-501(1)(f)(i)(B)~~]	[~~$ 500 - $ 2,000~~]	[~~$ 2,000 - $ 10,000~~]
[~~(9)~~]	[~~58-1-501(2)(m)(ii)~~]	[~~$500 - $ 2,000~~]	[~~$ 2,000 - $ 10,000~~]
[~~(10)~~]	[~~58-1-501(2)(a)~~]	[~~$ 100 - $ 2,000~~]	[~~$ 2,000 - $ 10,000~~]
[~~(11)~~]	[~~58-1-501(2)(b)~~]	[~~$ 500 - $ 2,000~~]	[~~$ 2,000 - $ 10,000~~]
[~~(12)~~]	[~~58-1-501(2)(c)~~]	[~~$ 500 - $ 2,000~~]	[~~$ 2,000 - $ 10,000~~]
[~~(13)~~]	[~~58-1-501(2)(d)~~]	[~~$ 100 - $ 500~~]	[~~$ 200 - $ 1,000~~]
[~~(14)~~]	[~~58-1-501(2)(e)~~]	[~~$ 100 - $ 500~~]	[~~$ 200 - $ 1,000~~]
[~~(15)~~]	[~~58-1-501(2)(f)~~]	[~~$ 100 - $ 500~~]	[~~$ 200 - $ 1,000~~]
[~~(16)~~]	[~~58-1-501(2)(g)~~]	[~~$ 500 - $ 2,000~~]	[~~$ 2,000 - $ 10,000~~]
[~~(17)~~]	[~~58-1-501(2)(h)~~]	[~~$ 100 - $ 500~~]	[~~$ 200 - $ 1,000~~]
[~~(18)~~]	[~~58-1-501(2)(i)~~]	[~~$ 100 - $ 500~~]	[~~$ 200 - $ 1,000~~]
[~~(19)~~]	[~~58-1-501(2)(j)~~]	[~~$ 100 - $ 500~~]	[~~$ 200 - $ 1,000~~]
[~~(20)~~]	[~~58-1-501(2)(k)~~]	[~~$ 100 - $ 1,000~~]	[~~$ 500 - $ 2,000~~]
[~~(21)~~]	[~~58-1-501(2)(l)~~]	[~~$ 100 - $ 500~~]	[~~$ 200 - $ 1,000~~]

[~~(22)~~]	[~~58-1-501(2)(n)~~]	[~~$ 500 - $ 2,000~~]	[~~$ 2,000 - $ 10,000~~]
(7)	58-1-501(1)(f)(i)(B)	$ 500 - $ 2,000	$ 2,000 - $ 10,000
(8)	58-1-501(1)(g)	$ 500 - $ 2,000	$ 2,000 - $ 10,000
(9)	58-1-501(2)(a)(i)	$ 100 - $ 2,000	$ 2,000 - $ 10,000
(10)	58-1-501(2)(a)(ii)	$ 500 - $ 2,000	$ 2,000 - $ 10,000
(11)	58-1-501(2)(a)(iii)	$ 500 - $ 2,000	$ 2,000 - $ 10,000
(12)	58-1-501(2)(a)(iv)	$ 100 - $ 500	$ 200 - $ 1,000
(13)	58-1-501(2)(a)(v)	$ 100 - $ 500	$ 200 - $ 1,000
(14)	58-1-501(2)(a)(vi)	$ 100 - $ 500	$ 200 - $ 1,000
(15)	58-1-501(2)(a)(vii)	$ 500 - $ 2,000	$ 2,000 - $ 10,000
(16)	58-1-501(2)(a)(viii)	$ 100 - $ 500	$ 200 - $ 1,000
(17)	58-1-501(2)(a)(ix)	$ 100 - $ 500	$ 200 - $ 1,000
(18)	58-1-501(2)(a)(x)	$ 100 - $ 500	$ 200 - $ 1,000
(19)	58-1-501(2)(a)(xi)	$ 100 - $ 1,000	$ 500 - $ 2,000
(20)	58-1-501(2)(a)(xii)	$ 100 - $ 500	$ 200 - $ 1,000
(21)	58-1-501(2)(a)(xiii)(A)	$ 500 - $ 2,000	$ 2,000 - $ 10,000
(22)	58-1-501(2)(a)(xiii)(B)	$500 - $ 2,000	$ 2,000 - $ 10,000
(23)	58-1-501(2)(a)(xiv)	$ 500 - $ 2,000	$ 2,000 - $ 10,000
(24)	58-1-501(2)(a)(xv)	$ 500 - $ 2,000	$ 2,000 - $ 10,000
(25)	58-1-501(2)(a)(xvi)	$ 500 - $ 2,000	$ 2,000 - $ 10,000
[~~(23)~~](26)	58-1-501.5	$ 500 - $ 2,000	$ 2,000 - $ 10,000
[~~(24)~~](27)	R156-1-501(1)	$ 500 - $ 2,000	$ 2,500 - $ 10,000
[~~(25)~~](28)	R156-1-501(2)	$ 500 - $ 2,000	$ 2,500 - $ 10,000
[~~(26)~~](29)	R156-1-501(3)	$ 500 - $ 2,000	$ 2,500 - $ 10,000
[~~(27)~~](30)	R156-1-501(4)	$ 500 - $ 2,000	$ 2,500 - $ 10,000
[~~(28)~~](31)	R156-1-501(5)	$ 500 - $ 2,000	$ 2,500 - $ 10,000
[~~(29)~~](32)	R156-1-501(6)	$ 500 - $ 2,000	$ 2,500 - $ 10,000
[~~(30)~~](33)	58-17b-501(1)	$ 500 - $ 2,000	$ 5,000
[~~(31)~~](34)	58-17b-501(2)	$ 100 - $ 1,000	$ 500 - $ 2,000
[~~(32)~~](35)	58-17b-501(3)(a)	$ 500 - $ 2,000	$ 2,000 - $ 10,000
[~~(33)~~](36)	58-17b-501(3)(b)	$ 500 - $ 2,000	$ 2,000 - $ 10,000
[~~(34)~~](37)	58-17b-501(4)	$ 1,000 - $ 5,000	$ 10,000
[~~(35)~~](38)	58-17b-501(5)	$ 100 - $ 500	$ 200 - $ 1,000
[~~(36)~~](39)	58-17b-501(6)	$ 500 - $ 2,000	$ 2,000 - $ 10,000
[~~(37)~~](40)	58-17b-501(7)	$ 500 - $ 2,000	$ 2,000 - $ 10,000
[~~(38)~~](41)	58-17b-501(8)	$ 500 - $ 2,000	$ 2,500 - $ 10,000
[~~(39)~~](42)	58-17b-501(9)	$ 500 - $ 1,000	$ 1,500 - $ 5,000
[~~(40)~~](43)	58-17b-501(10)	$ 500 - $ 2,000	$ 2,500 - $ 10,000
[~~(41)~~](44)	58-17b-501(11)	$ 500 - $ 2,000	$ 2,500 - $ 10,000
[~~(42)~~](45)	58-17b-501(12)	$ 1,000 - $ 5,000	$ 10,000
[~~(43)~~](46)	58-17b-501(13)	$ 100 - $ 500	$ 1,000 - $ 2,500
[~~(44)~~](47)	58-17b-502(1)(a)	$ 500 - $ 2,000	$ 2,500 - $ 10,000
[~~(45)~~](48)	58-17b-502(1)(b)	$ 2,500 - $ 5,000	$ 5,500 - $ 10,000
[~~(46)~~](49)	58-17b-502(1)(c)	$ 1,000 - $ 5,000	$ 10,000
[~~(47)~~](50)	58-17b-502(1)(d)	$ 500 - $ 2,000	$ 2,500 - $ 10,000
[~~(48)~~](51)	58-17b-502(1)(e)	$ 1,000 - $ 5,000	$ 10,000
[~~(49)~~](52)	58-17b-502(1)(f)	$ 500 - $ 2,000	$ 2,500 - $ 10,000
[~~(50)~~](53)	58-17b-502(1)(g)	$ 500 - $ 2,000	$ 2,500 - $ 10,000
[~~(51)~~](54)	58-17b-502(1)(h)	$ 100 - $ 500	$ 500 - $ 1,000
[~~(52)~~](55)	58-17b-502(1)(i)	$ 500 - $ 2,000	$ 2,000 - $ 10,000
[~~(53)~~](56)	58-17b-502(1)(j)	$ 100 - $ 500	$ 500 - $ 1,000
[~~(54)~~](57)	58-17b-502(1)(k)	$ 100 - $ 500	$ 2,000 - $ 10,000
[~~(55)~~](58)	58-17b-502(1)(l)	$ 100 - $ 500	$ 500 - $ 1,000

[~~(56)~~](59)	58-17b-502(1)(m)	$ 500 - $ 1,000	$ 2,500 - $ 5,000
[~~(57)~~](60)	58-17b-502(1)(n)	$ 100 - $ 500	$ 500 - $ 1,000
[~~(58)~~](61)	58-17b-502(1)(o)	$ 100 - $ 500	$ 500 - $ 1,000
[~~(59)~~](62)	58-17b-502(1)(p)	$ 2,500 - $ 5,000	$ 5,000 - $ 10,000
[~~(60)~~](63)	R156-17b-502(1)	$ 250 - $ 500	$ 2,000 - $ 10,000
[~~(61)~~](64)	R156-17b-502(2)(a)	$ 250 - $ 500	$ 500 - $ 750
[~~(62)~~](65)	R156-17b-502(2)(b)	$ 500 - $ 2,000	$ 2,500 - $ 10,000
[~~(63)~~](66)	R156-17b-502(3)	$ 100 - $ 500	$ 500 - $ 1,000
[~~(64)~~](67)	R156-17b-502(4)	$ 50 - 100	$ 200 - $ 300
[~~(65)~~](68)	R156-17b-502(5)	$ 100 - $ 200	$ 200 - $ 500
[~~(66)~~](69)	R156-17b-502(6)	$ 500 - $ 1,000	$ 2,000 - $ 10,000
[~~(67)~~](70)	R156-17b-502(7)	$ 500 - $ 2,000	$ 2,000 - $ 10,000
[~~(68)~~](71)	R156-17b-502(8)	$ 100 - $ 250	$ 300 - $ 500
(72)	R156-17b-502(9)	$250 - $1,000	$ 500 - $ 5,000
[~~(69)~~](73)	R156-17b-502[~~(9)(a)~~](10)(a)	$ 50 - $ 100	$ 250 - $ 500
[~~(70)~~](74)	R156-17b-502[~~(9)(b)~~](10)(b)	$ 250 - $ 500	$ 750 - $ 1,000
[~~(71)~~](75)	[R156-17b-502[~~(10)~~](11)	$ 500 - $ 2,000	$ 2,000 - $ 10,000
[~~(72)~~]	[~~R156-17b-502(11)~~]	[~~$ 100 - $ 500~~]	[~~$ 500 - $ 1,000~~]
[~~(73)~~](76)	R156-17b-502(12)(a)	$ 100 - $ 250	$ 500 - $ 2,500
[~~(74)~~](77)	R156-17b-502(12)(b)	$ 250 - $ 1,000	$ 500 - $ 5,000
[~~(75)~~](78)	R156-17b-502(13)(a)	$ 50 - $ 100	$ 250 - $ 500
[~~(76)~~](79)	R156-17b-502(13)(b)	$ 250 - $ 500	$ 1,000 - $ 2,000
[~~(77)~~](80)	R156-17b-502(14)(a)	$ 500 - $ 2,500	$ 5,000 - $ 10,000
[~~(78)~~](81)	R156-17b-502(14)(b)	$ 2,000 per occurrence	
[~~(79)~~](82)	R156-17b-502(15)	double original penalty, up to $ 10,000	
[~~(80)~~](83)	R156-17b-502(16)	$ 500 - $ 2,000	$ 2,000 - $ 10,000
[~~(81)~~](84)	R156-17b-502(17)	$ 1,000 - $ 5,000	$ 10,000
[~~(82)~~](85)	R156-17b-502(18)	$ 500 - $ 2,500	$ 5,000 - $ 10,000
[~~(83)~~](86)	R156-17b-502(19)	$ 100 - $ 500	$ 200 - $ 1,000
[~~(84)~~](87)	R156-17b-502(20)	$ 100 - $ 500	$ 200 - $ 1,000
[~~(85)~~](88)	R156-17b-502(21)	$ 100 - $ 500	$ 200 - $ 1,000
[~~(86)~~](89)	R156-17b-502(22)	$ 500 - $ 2,000	$ 2,000 - $ 10,000
[~~(87)~~](90)	R156-17b-502(23)(a)	$ 100 - $ 300	$ 500 - $ 1,000
[~~(88)~~](91)	R156-17b-502(23)(b)	$ 250 - $ 500	$ 500 - $ 1,250
[~~(89)~~](92)	R156-17b-502(24)	$ 100 - $ 500	$ 500 - $ 1,000
[~~(90)~~](93)	R156-17b-502(25)	$ 500 - $ 2,000	$ 2,500 - $ 10,000
[~~(91)~~](94)	R156-17b-502(26)	$ 500 - $ 2,000	$ 2,500 - $ 10,000
[~~(92)~~](95)	58-37-8	$ 1,000-$ 5,000	$ 5,000 - $ 10,000
[~~(93)~~](96)	R156-37-502(1)(a)	$ 500 - $ 2,000	$ 2,500 - $ 10,000
[~~(94)~~](97)	R156-37-502(1)(b)	$ 500 - $ 2,000	$ 2,500 - $ 10,000
[~~(95)~~](98)	R156-37-502(2)	$ 500 - $ 2,000	$ 2,500 - $ 10,000
[~~(96)~~](99)	R156-37-502(3)	$ 500 - $ 2,000	$ 2,500 - $ 10,000
[~~(97)~~](100)	R156-37-502(4)	$ 500 - $ 2,000	$ 2,500 - $ 10,000
[~~(98)~~](101)	R156-37-502(5)	$ 500 - $ 2,000	$ 2,500 - $ 10,000
[~~(99)~~](102)	R156-37-502(6)	$ 500 - $ 2,000	$ 2,500 - $ 10,000
[~~(100)~~](103)	R156-37-502(7)	$ 500 - $ 2,000	$ 2,500 - $ 10,000
[~~(101)~~](104)	R156-37-502(8)	$ 500 - $ 2,000	$ 2,500 - $ 10,000
[~~(102)~~](105)	Any other conduct that constitutes Unprofessional or Unlawful conduct	$ 100 - $ 500	$ 200 - $ 1,000

R156-17b-502. Unprofessional Conduct.

"Unprofessional conduct" includes:

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

(2)(a) failing to comply with the USP-NF [~~Chapter~~]≤795≥, if applicable to activities performed; or

(b) failing to comply with the USP-NF [~~Chapter~~]≤797≥, if applicable to activities performed;

(3) failing to comply with continuing education requirements;

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

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

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

(7) failing to comply with administrative inspections;

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

(9) providing false information on a self-audit report;

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

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

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

(12)(a) as a pharmacist, practicing pharmacy with an inappropriate pharmacist to pharmacy intern ratio under Subsection R156-17b-606(3)[~~(1)(d),~~] or pharmacist to pharmacy technician trainee ratio under Subsection R156-17b-601(4); or

(b) as a pharmacy, practicing pharmacy with an inappropriate pharmacist to pharmacy intern ratio under Subsection R156-17b-606(3)[~~(1)(d),~~] or pharmacist to pharmacy technician trainee ratio under Subsection R156-17b-601(4);

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

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

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

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

(15) failing to timely pay an administrative fine;

(16) failing to comply with the PIC, consulting pharmacist, RDPIC or DMPIC standards under 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 under 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 consulting pharmacist, designated representative, responsible party, PIC, RDPIC, or DMPIC information to the Division within 30 days of a change in consulting pharmacist, designated representative, responsible party, PIC, RDPIC or DMPIC;

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

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

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

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

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

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

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

Under Subsection 58-17b-102[~~(56)~~](57), this section defines 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;

(k) receiving new prescription drug orders when communicating telephonically or electronically, if the original information is recorded so the pharmacist may review the prescription drug order as transmitted, including accepting new prescription drug orders saved on voicemail for a pharmacist to review;

(l) transferring prescriptions under Subsections 58-17b-604(4)(a), 58-17b-604, and R156-17b-[~~609~~]612;

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

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

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

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

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

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

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

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

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

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

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

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

(II) process for supervising technicians who check medications;

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

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

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

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

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

(2) A pharmacy technician may not:

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

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

(c) perform a drug utilization review;

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

(e) dispense a drug; or

(f) counsel a patient with respect to a prescription drug.

(3) A pharmacy technician may administer vaccines and emergency medications pursuant to delegation by a pharmacist under the Vaccine Administration Protocol, if the pharmacy technician:

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

(b) is under direct, on-site supervision by the delegating pharmacist as defined in Subsection R156-1-102a(1)(a)[~~(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 Section R156-17b-309.

(4) A pharmacy technician trainee:

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

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

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

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

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

(1) Under Subsection 58-17b-102[~~(71)(a)~~](72)(a), supportive personnel may assist in 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 may not enter information into a patient prescription profile or accept verbal refill information.

(3) Under Subsection 58-17b-102[~~(71)(b)~~](72)(b), supportive personnel shall be supervised by a licensed pharmacist or DMP who is:

(a) present in the area where the individual being supervised is performing services; and

(b) immediately available to assist the individual being supervised in the services being performed, except for the delivery of pre-filled prescriptions under Subsection (1)(g).

(4) Under 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 may not provide support services in a pharmacy.

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

Under Subsection 58-17b-601(1) and Section 58-17b-613, this section establishes guidelines for providing patient counseling.[~~-in Section 58-17b-613 include the following:~~]

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

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

(2) A pharmacy facility shall verbally[~~orally~~] offer the patient or patient's agent[~~to~~] counseling as described in Subsection (1), but is not required to provide counseling to a patient or patient's agent who refuses counseling.

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

(a) the name and description of the prescription drug;

(b) the dosage form, dose, route of administration and duration of drug therapy;

(c) the intended use of the drug, when known, and expected action;

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

(e) any common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

(f) the techniques for self-monitoring drug therapy;

(g) the proper storage;

(h) the prescription refill information;

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

(j) any pharmacist comments relevant to the individual's drug therapy, including any other information specific to the patient or drug; and

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

(4)(a) The offer to counsel shall be documented.

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

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

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

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

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

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

(b) provide any other written information and counseling as described in [~~Section 26-62-106~~]Section 26B-4-506.

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

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

(a)(i) USP [~~General Chapter~~]<797> Pharmaceutical Compounding - Sterile Preparations[~~:~~];

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

(b) USP [~~General Chapter~~]<795> Pharmaceutical Compounding - Nonsterile Preparations; and

(c) USP [~~General Chapter~~]<825> Radiopharmaceuticals - Preparation, Compounding, Dispensing, and Repackaging.

(2) These operating standards shall apply:

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

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

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

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

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

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

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

(iii) a compounding aseptic containment isolator (CACI); or

(iv) a laminar airflow workbench (LAFW), compounding aseptic isolator (CAI) may be used for the compounding of non-antineoplastic HD in accordance with a hazardous drug risk assessment as defined in USP <800> Section 2 Box 1;

(b)(i) clearly mark and identify hazardous API;

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

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

(c) adhere to the requirements in USP <800> except the following Sections:

(i) 1. INTRODUCTION AND SCOPE;

(ii) 3. TYPES OF EXPOSURE;

(iii) 5. FACILITIES AND ENGINEERING CONTROLS;

(iv) 6. ENVIRONMENTAL QUALITY AND CONTROL;

(v) 14. ADMINISTERING;

(vi) 16. SPILL CONTROL;

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

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

(B) a licensed pharmacy need not adhere to:

(I) environmental monitoring including wipe sampling; and

(II) medical surveillance; and

(viii) 18. MEDICAL SURVEILLANCE.

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

In accordance with Subsection 58-17b-601(1), th[~~e following~~]is section establishes the operating standards [~~apply to~~]for pharmacies that engage in central prescription processing as defined in Subsection 58-17b-102(9)[~~:~~].

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

(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)(a) "Non drug or device handling central prescription processing pharmacies", as defined in Subsection R156-17b-102([~~40~~]43), shall be licensed as Class E pharmacies.

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

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

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

(2) A remote dispensing pharmacy shall:

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

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

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

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

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

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

(5)[~~–~~](a) At any time that a remote dispensing pharmacy is open and available to serve patients, its pharmacy technicians shall be physically or electronically supervised by a pharmacist from the supervising pharmacy, under Subsection 58-17b-102[~~(70)~~](71).

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

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

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

(e)(i) Adequate supervision by a 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.

(ii) A supervising pharmacist may not delegate supervision to any other person.

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

(a) provides comprehensive[~~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 Subsection [~~R156-17b-102(64)~~]R156-17b-102(67).

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

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

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

(b)(i) The plan shall 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.

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

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

(9)(a)(i) The remote dispensing pharmacy's security system shall track entries into the remote dispensing pharmacy.

(ii) 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.

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

(ii) 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)(i) The RDPIC shall oversee documented monthly inspections of the remote dispensing pharmacy.

(ii) Documentation of the inspections shall be kept for five years, and shall include:

(A) maintenance and reconciliation of any controlled substance;

(B) a perpetual inventory of Schedule II controlled substances;

(C) temperature logs of the refrigerator and freezer that hold medications; and

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

R156-17b-617g. Operating Standards - Class E Pharmacy - Third Party Logistics Provider.

(1) A third party logistics provider shall comply with DSCSA standards.[~~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.

[~~In accordance with~~]This section establishes training standards under Subsections 58-17b-102(53), [~~(56)~~](57), and [~~(57)~~](58), and 58-17b-502(1)(i)(i).[~~:~~]

(1) A pharmacist or pharmacy intern who will administer a prescription drug or device shall first complete the following appropriate training[~~- prior to engaging in administration~~]:

(a) current Basic Life Support (BLS) certification;

(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;

(d) 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

(e) the management of an anaphylactic reaction.

(2) A pharmacy technician who will administer a prescription drug or device shall first complete the appropriate training described in Subsections (1)(a), (b), and (e)[~~- prior to engaging in administration~~].

(3) Sources for the appropriate training include:

(a) ACPE approved programs;

(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.

(4) 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~~]under Section R156-17b-309.

(5) The "Vaccine Administration Protocol: Standing Order to Administer Immunizations and Emergency Medications", adopted [~~March 26, 2019~~]September, 2023, by the Division in collaboration with the [~~Utah State~~]Board of Pharmacy and the Utah Medical Licensing Board[~~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-621b. Operating Standards - Pharmacist and Pharmacy Intern Dispensing of a Self-Administered Hormonal Contraceptive - Training.

[~~In accordance with~~]This section establishes training standards under Subsection 58-17b-502(1)(n) and Section [~~26-64-106.~~]26B-4-506.

(1) Before[~~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 they obtained their required training before[~~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[~~-~~]; and

(c) review the Utah Guidance for Self-Administered Hormonal Contraceptives which can be found on the Division's website at https://dopl.utah.gov/pharmacy/resources.

[~~(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[~~(18)~~](21)(c), a formal or on-the-job dispensing training program completed by a DMP designee is one that covers the following topics to the extent that the topics are relevant and current to the DMP practice where the DMP designee is employed:

(a) role of the DMP designee;

(b) laws affecting prescription drug dispensing;

(c) pharmacology including the identification of drugs by trade and generic names, and therapeutic classifications;

(d) pharmaceutical terminology, abbreviations and symbols;

(e) pharmaceutical calculations;

(f) drug packaging and labeling;

(g) computer applications in the pharmacy;

(h) sterile and non-sterile compounding;

(i) medication errors and safety;

(j) prescription and order entry and fill process;

(k) pharmacy inventory management; and

(l) pharmacy billing and reimbursement.

(2) Documentation demonstrating successful completion of a formal or on-the-job dispensing training program shall include the following information:

(a) name of individual trained;

(b) name of individual or entity that provided training;

(c) list of topics covered during the training program; and

(d) training completion date.

R156-17b-623. Standards - Approved Cosmetic Drugs and Injectable Weight Loss Drugs for Dispensing Medical Practitioners.

The drugs that may be dispensed by a DMP in accordance with Subsection 58-17b-802(1) and Section 58-17b-803 are limited to:

(1) the following cosmetic drugs:

(a) Latisse or generic equivalent; and

(b) the injectable weight loss drug human chorionic gonadotropin; and

(2) the following legend, non-controlled drugs:[~~approved under Section R156-83-306 for prescribing by an online prescriber.~~]

(a) hormonal based contraception unless using except injectable or implantable methods;

(b) hydroquinone up to 4%; and

(c) tretinoin up to 0.1%.

R156-17b-1005. Operating Standards -- Standing Prescription Orders for Emergency Medications Use as School Stock.

(1) In accordance with Subsection 58-17b-601(1), the Division approves all standing orders required by statute and issued by the Utah Department of Health and Human Services relating to dispensing of emergency use medication to be held as school stock.

(2) Authorized standing orders referenced in Subsection 1005(1) can be found at https://dopl.utah.gov/pharmacy/resources/.

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