Real Time Reporting to the Utah Controlled Substance Database

Goal:

Two-way real time communication between pharmacies and the Utah Controlled Substance Database to promote the safe prescribing and dispensing of controlled substances.

Process:

Pharmacies will submit prescription data at the time of dispensing using NCPDP script standard (HIPPA compliant) to a third party database. The third party database will organize the data and submit it to the Utah CSD. Utilizing information already in the third party database and information from the state, the pharmacy will receive appropriate DUR information on controlled substance utilization.

Timeline:

- 2-4 month pilot program
- Lobby to change the rules to promote real time reporting
- Educate pharmacies about the different options of reporting
- June 2015 – Real-time reporting is available to all pharmacies

Costs:

The majority of the costs will be shouldered by the pharmacies on a cost per claim basis. The state will need to provide a technician during for process improvement and troubleshooting.

Specific Needs from the State:

- Approval for the pilot program
- Agreement to work with us to develop the efficient transfer of information
- Agreement to provide information from the database for DUR utilization
- Change the rules to mandate real time reporting

#1

	2013	2014	Oct-14
Administrative Filings	37	47	3
Criminal Filing/Felony	3	0	0
Letter of Concern	60	103	13
Referred to Diversion	1	2	0
PR/Outreach	3	4	0
Cases Received	710	354	89
Case Assigned	676	342	89
Closed Cases	731	387	79
Citations Issued	103	34	8
Pharmacy Inspections	225	214	47
Pharmacy Alerts	191	208	29
Dr. Shopper/Law Enforcement Letters	209	463	62

NOTES: Pharmacy Group	**Oct-14**
Administrative Action	Pharmacy Technician, Jamie West entered into a Stipulation surrendering her license for prescription fraud.
Administrative Action	Pharmacist, Craig Marx entered into a Stipulation surrendering his license for drug diversion.
Administrative Action	Pharmacy Technician, Robert Smith entered into a Stipulation and Order. Smith's license was revocted, revocation was stayed, and Smith is currently on Probation for other criminal conduct.
Citation	The Medicine Shoppe was issued a Citation with a $2,000 fine for Pharmacy Violations found during a Random Inspection.
Citation	The Medicine Shoppe was issued a Citation with a $1,050 fine for expired drugs found during a Random Inspection.
Citation	Walgreens Pharmacy was issued a Citation with a $1,050 fine for Pharmacy Violations found during a Random Inspection.
Citation	Skyline Pharmacy was issued a Citation with a $1,050 fine for Pharmacy Violations found during a Random Inspection.
Citation	Terrells Thriftway was issued a Citation with a $1,050 fine for Pharmacy Violations found during a Random Inspection.
Citation	Kmart Pharmacy was issued a Citation with a $1,050 fine for Pharmacy Violations found during a Random Inspection.
Citation	Walgreens Pharmacy was issued a Citation with a $1,050 fine for Pharmacy Violations found during a Random Inspection.
Citation	Cottonwood Apothecary was issued a Citation with a $1,050 fine for Pharmacy Violations found during a Random Inspection.

Add the following:

▲⟨17⟩ PRESCRIPTION CONTAINER LABELING ▲

INTRODUCTION

Medication misuse has resulted in more than 1 million adverse drug events per year in the United States. Patients' best source (and often only source) of information regarding the medications they have been prescribed is on the prescription container label. Although other written information and oral counseling sometimes may be available, the prescription container label must fulfill the professional obligations of the prescriber and pharmacist. These obligations include giving the patient the most essential information needed to understand how to safely and appropriately use the medication and to adhere to the prescribed medication regimen.

Inadequate understanding of prescription directions for use and auxiliary information on dispensed containers is widespread. Studies have found that 46% of patients misunderstood one or more dosage instructions, and 56% misunderstood one or more auxiliary warnings. The problem of misunderstanding is particularly troublesome in patients with low or marginal literacy and in patients receiving multiple medications that are scheduled for administration using unnecessarily complex, nonstandardized time periods. In one study, patients with low literacy were 34 times more likely to misinterpret prescription medication warning labels. However, even patients with adequate literacy often misunderstand common prescription directions and warnings. In addition, there is great variability in the actual auxillary warning and supplemental instructional information applied by individual practitioners to the same prescription. The specific evidence to support a given auxiliary statement often is unclear, and patients often ignore such information. The essential need for, and benefit of, auxiliary label information (both text and icons) in improving patient understanding about safe and appropriate use of their medications vs. explicit simplified language alone require further study.

Lack of universal standards for labeling on dispensed prescription containers is a root cause for patient misunderstanding, nonadherence, and medication errors. On May 18, 2007, the USP Safe Medication Use Expert Committee established an Advisory Panel to: 1) determine optimal prescription label content and format to promote safe medication use by critically reviewing factors that promote or distract from patient understanding of prescription medication instructions and 2) create universal prescription label standards for format/appearance and content/language.

In November 2009, the Health Literacy and Prescription Container Labeling Advisory Panel presented its recommendations to the Safe Medication Use Expert Committee, which then requested that USP develop patient-centered label standards for the format, appearance, content, and language of prescription medication instructions to promote patient understanding. These recommendations form the basis of this general chapter.

Note—These standards do not apply when a prescription drug will be administered to a patient by licensed personnel who are acting within their scope of practice.

PRESCRIPTION CONTAINER LABEL STANDARDS TO PROMOTE PATIENT UNDERSTANDING

Organize the prescription label in a patient-centered manner: Information shall be prioritized in a way that best reflects how most patients seek out and understand medication instructions. Prescription container labeling should feature only the most important patient information needed for safe and effective understanding and use.

Emphasize instructions and other information important to patients: Prominently display information that is critical for patients' safe and effective use of the medicine. At the top of the label, specify the patient's name, drug name (spell out full generic and brand name) and strength, and explicit clear directions for use in simple language.

The prescription directions should follow a standard format so the patient can expect that each element will be in a regimented order each time a prescription is received.

Other less critical but important content (e.g., pharmacy name and phone number, prescriber name, fill date, refill information, expiration date, prescription number, drug quantity, physical description, and evidence-based auxiliary information) should not supersede critical patient information. Such less critical information should be placed away from dosing instructions (e.g., at the bottom of the label or in another less prominent location) because it distracts patients, which can impair their recognition and understanding.

Simplify language: Language on the label should be clear, simplified, concise, and familiar, and should be used in a standardized manner. Only common terms and sentences should be used. Do not use unfamiliar words (including Latin terms) or medical jargon.

Use of readability formulas and software is not recommended to simplify short excerpts of text like those on prescription labels. Instead, use simplified, standardized sentences that have been developed to ensure ease of understanding the instructions correctly (by seeking feedback from samples of diverse consumers).

Give explicit instructions: Instructions for use (i.e., the SIG or signatur) should clearly separate the dose itself from the timing of each dose in order to explicitly convey the number of dosage units to be taken and when (e.g., specific time periods each day such as morning, noon, evening, and bedtime). Instructions shall include specifics on time periods. Do not use alphabetic characters for numbers. For example, write "Take 2 tablets in the morning and 2 tablets in the evening," rather than "Take two tablets twice daily."

Whenever available, use standardized directions (e.g., write "Take 1 tablet in the morning and 1 tablet in the evening," if the prescription reads b.i.d.). Vague instructions based on dosing intervals such as twice daily or 3 times daily or hourly intervals such as every 12 hours generally should be avoided because such instructions are implicit rather than explicit, they may involve numeracy skills, and patient interpretation may vary from prescriber intent. Although instructions that use specific hourly times (e.g., 8 a.m. and 10 p.m.) may seem to be more easily understood than implicit vague instructions recommending dosing by precise hours of the day is less readily understood and may present greater adherence issues due to individual lifestyle patterns, e.g., shift work, than more general time frames such as in the morning, in the evening, after breakfast, with lunch, or at bedtime. Consistent use of the same terms should help avoid patient confusion.

Ambiguous directions such as "take as directed" should be avoided unless clear and unambiguous supplemental instructions and counseling are provided (e.g., directions for use that will not fit on the prescription container label). A clear statement referring the patient to such supplemental materials should be included on the container label.

Include purpose for use.—If the purpose of the medication is included on the prescription, it should be included on the prescription container label unless the patient prefers that it not appear. Always ask patients their preference when prescriptions are submitted for filling. Confidentiality and FDA approval for intended use (e.g., labeled vs. off-label use) may limit inclusion of the purpose on labels. Current evidence supports inclusion of purpose-for-use language in clear, simple terms (e.g., "for high blood pressure" rather than "for hypertension").

Limit auxiliary information.—Auxiliary information on the prescription container label should be evidence-based in simple explicit language that is minimized to avoid distracting patients with nonessential information. Most patients, particularly those with low literacy, pay little attention to auxiliary information. The information should be presented in a standardized manner and should be critical for patient understanding and safe medication use (e.g., warnings and critical administration alerts). Icons are frequently misunderstood by patients. In addition, icons that provide abstract imagery for messages that are difficult to visually depict may be ineffective at improving understanding compared with simplified text alone. Use only icons for which there is adequate evidence, through consumer testing, that they improve patient understanding about correct use. Evidence-based auxiliary information, both text and icons, should be standardized so that it is applied consistently and does not depend on individual practitioner choice.

Address limited English proficiency.—Whenever possible, the directions for use on a prescription container label should be provided in the patient's preferred language. Otherwise there is a risk of misinterpretation of instructions by patients with limited English proficiency, which could lead to medication errors and adverse health outcomes. Additionally, whenever possible, directions for use should appear in English as well to facilitate counseling; the drug name shall be in English so that emergency personnel and other intermediaries can have quick access to the information.

Translations of prescription medication labels should be produced using a high-quality translation process. An example of a high-quality translation process is:

- Translation by a trained translator who is a native speaker of the target language
- Review of the translation by a second trained translator and reconciliation of any differences
- Review of the translation by a pharmacist who is a native speaker of the target language and reconciliation of any differences
- Testing of comprehension with target audience

If a high-quality translation process cannot be provided, labels should be printed in English and trained interpreter services used whenever possible to ensure patient comprehension. The use of computer-generated translations should be limited to programs with demonstrated quality because dosage instructions can be inconsistent and potentially hazardous. Standardized translated instructions and technology advances are needed to ensure the accuracy and safety of prescription container labeling for patients with low English proficiency.

Improve readability.—Labels should be designed and formatted so they are easy to read. Currently no strong evidence supports the superiority in legibility of serif vs. sans serif typefaces, so simple uncondensed fonts of either type can be used.

Optimize typography by using the following techniques:

- High-contrast print (e.g., black print on white background).
- Simple, uncondensed familiar fonts with sufficient space within letters and between letters (e.g., Times Roman or Arial).
- Sentence case (i.e., punctuated like a sentence in English: initial capital followed by lower-case words, except proper nouns).
- Large font size (e.g., minimum 12-point Times Roman or 11-point Arial) for critical information. Note that point size is not the actual size of the letter, so 2 fonts with the same nominal point size can have different actual letter sizes. X-height, the height of the lower-case x in typeface, has been used as a more accurate indicator of apparent size than point size. For example, for a given point size, the x-height and apparent size of Arial are actually bigger than those for Times Roman. Do not use type smaller than 10-point Times Roman or equivalent size of another font. Older adults, in particular, have difficulty reading small print.
- Adequate white space between lines of text (25%–30% of the point size).
- White space to distinguish sections on the label such as directions for use vs. pharmacy information.
- Horizontal text only.

Other measures that can also improve readability:

- If possible, minimize the need to turn the container in order to read lines of text.
- Never truncate or abbreviate critical information.
- Highlighting, bolding, and other typographical cues should preserve readability (e.g., high-contrast print and light color for highlighting) and should emphasize patient-centric information or information that facilitates adherence (e.g., refill ordering).
- Limit the number of colors used for highlighting (e.g., no more than one or two).
- Use of separate lines to distinguish when each dose should be taken.

Address visual impairment.

- Provide alternative access for visually impaired patients (e.g., tactile, auditory, or enhanced visual systems that may employ advanced mechanics of assistive technology).

▲ *USP36*

(5)

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

R156-17b-102. Definitions.

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

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

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

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

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

(3) "Analytical laboratory":

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

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

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

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

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

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

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

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

(10) "Co-licensed partner or product" means an instance where two or more parties have the right to engage in the manufacturing and/or marketing of a prescription drug, consistent with FDA's implementation of the Prescription Drug Marketing Act.

(11) "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.

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

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

(14) "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.

(15) "Device" means an instrument, apparatus, implement, machine, contrivance, implant, or other similar or related article, including any component part or accessory, which is required under Federal law to bear the label, "Caution: Federal or State law requires dispensing by or on the order of a physician."

(16) "DMP" means a dispensing medical practitioner licensed under Section 58-17b, Part 8.

(17) "DMP designee" means an individual acting under the direction of a DMP who:

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

(A) Chapter 67, Utah Medical Practice Act;

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

(C) Chapter 70a, Physician Assistant Act;

(D) Chapter 31b, Nurse Practice Act;

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

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

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

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

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

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

([~~17~~]18) "Drop shipment" means the sale of a prescription drug to a pharmaceutical wholesaler by the manufacturer of the drug; by the manufacturer's co-licensed product partner, third party logistics provider, or exclusive distributor; or by an authorized distributor of record that purchased the product directly from the manufacturer or from one of these entities; whereby:

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

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

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

([~~17~~]19) "Drug therapy management" means the review of a drug therapy regimen of a patient by one or more pharmacists for the purpose of evaluating and rendering advice to one or more practitioners regarding adjustment of the regimen.

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

([~~19~~]21) "Durable medical equipment" or "DME" means equipment that:

(a) can withstand repeated use;

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

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

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

(e) may include devices and medical supplies.

([~~20~~]22) "Entities under common administrative control" means an entity holds the power, actual as well as legal to influence the management, direction, or functioning of a business or organization.

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

([~~22~~]24) "ExCPT", as used in this rule, means the Exam for the Certification of Pharmacy Technicians.

([~~23~~]25) "FDA" means the United States Food and Drug Administration and any successor agency.

([24]26) "High-risk, medium-risk, and low-risk drugs" refers to the risk to a patient's health from compounding sterile preparations, as referred to in USP-NF Chapter 797, for details of determining risk level.

([~~25~~]27) "Hospice facility pharmacy" means a pharmacy that supplies drugs to patients in a licensed healthcare facility for terminal patients.

([~~26~~]28) "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.

([~~27~~]29) "Legend drug" or "prescription drug" means any drug or device that has been determined to be unsafe for self-medication or any drug or device that bears or is required to bear the legend:

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

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

(c) "Rx only".

([~~28~~]30) "Maintenance medications" means medications the patient takes on an ongoing basis.

([~~29~~]31) "Manufacturer's exclusive distributor" means an entity that contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer and who takes title to that manufacturer's prescription drug, but who does not have general responsibility to direct the drug's sale or disposition. Such manufacturer's exclusive distributor shall be licensed as a pharmaceutical wholesaler under this chapter and be an "authorized distributor of record" to be considered part of the "normal distribution channel".

([~~30~~]32) "Medical supplies" means items for medical use that are suitable for use in a health care facility or in the home and that are disposable or semi-disposable and are non-reusable.

([~~31~~]33) "MPJE" means the Multistate Jurisprudence Examination.

([~~32~~]34) "NABP" means the National Association of Boards of Pharmacy.

([~~33~~]35) "NAPLEX" means North American Pharmacy Licensing Examination.

([~~34~~]36) "Normal distribution channel" means a chain of custody for a prescription drug that goes directly, by drop shipment as defined in Subsection (16), or via intracompany transfer from a manufacturer; or from the manufacturer's co-licensed partner, third-party logistics provider, or the exclusive distributor to:

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

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

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

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

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

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

([~~35~~]37) "Other health care facilities" means any entity as defined in Utah Code Subsection 26-21-2(13)(a) or Utah Administrative Code R432-1-3(55).

([~~36~~]38) "Parenteral" means a method of drug delivery injected into body tissues but not via the gastrointestinal tract.

(39) "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 patient's authorized designee, one of the following facilities:

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

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

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

([~~37~~]40) "Pedigree" means a document or electronic file containing information that records each distribution of any given prescription drug.

([~~38~~]41) "PIC", as used in this rule, means the pharmacist-in-charge.

([~~39~~]42) "Prepackaged" or "Prepackaging" means the act of transferring a drug, manually or by use of an automated pharmacy system, from a manufacturer's or distributor's original container to another container in advance of receiving a prescription drug order or for a patient's immediate need for dispensing by a pharmacy or practitioner authorized to dispense in the establishment in which the prepackaging occurred.

([~~40~~]43) "Prescription files" means all hard-copy and electronic prescriptions that includes pharmacist notes or technician notes, clarifications or information written or attached that is pertinent to the prescription.

([~~41~~]44) "PTCB" means the Pharmacy Technician Certification Board.

([~~42~~]45) "Qualified continuing education", as used in this rule, means continuing education that meets the standards set forth in Section R156-17b-309.

([~~43~~]46) "Refill" means to fill again.

([~~44~~]47) "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.

([~~45~~]48) "Research facility" means a facility in which research takes place that has policies and procedures describing such research.

([~~46~~]49) "Responsible DMP" means a dispensing medical practitioner licensed under Section 58-17b, Part 8 that is designated by a dispensing medical practitioner clinic pharmacy to be responsible for activities of the pharmacy.

([~~46~~]50) "Reverse distributor" means a person or company that retrieves unusable or outdated drugs from a pharmacy [~~or pharmacist~~]for the purpose of removing those drugs from stock and destroying them.

([~~47~~]51) "Sterile products preparation facility" means any facility, or portion of the facility, that compounds sterile products using aseptic technique.

([~~48~~]52) "Supervisor" means a licensed pharmacist or DMP in good standing with the Division.

([~~49~~]53) "Third party logistics provider" means anyone who contracts with a prescription drug manufacturer to provide or coordinate warehousing, distribution, or other similar services on behalf of

a manufacturer, but does not take title to the prescription drug or have any authoritative control over the prescription drug's sale. Such third party logistics provider shall be licensed as a pharmaceutical wholesaler under this chapter and be an "authorized distributor of record" to be considered part of the "normal distribution channel".

([~~50~~]54) "Unauthorized personnel" means any person who is not participating in the operational processes of the pharmacy who in some way would interrupt the natural flow of pharmaceutical care.

([~~51~~]55) "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.

([~~52~~]56) "Unprofessional conduct", as defined in Title 58, Chapters 1 and 17b, is further defined, in accordance with Subsection 58-1-203(1)(e), in Section R156-17b-502.

([~~53~~]57) "USP-NF" means the United States Pharmacopeia-National Formulary (USP 37-NF 32), 2014 edition, which is official from May 1, 2014 through Supplement 1, dated August 1, 2014, which is hereby adopted and incorporated by reference.

([~~54~~]58) "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.

([~~55~~]59) "Wholesale distribution" means the distribution of drugs to persons other than consumers or patients, but does not include:

(a) intracompany sales or transfers;

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

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

(d) the distribution of drug samples;

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

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

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

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

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

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

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

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

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

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

Division.

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

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

R156-17b-302. Pharmacy Licensure Classifications - Pharmacist-in-Charge Requirements.

In accordance with Subsection 58-17b-302(4), the classification of pharmacies holding licenses are clarified as:

(1) A Class A pharmacy includes all retail operations located in Utah and requires a PIC.

(2) A Class B pharmacy includes an institutional pharmacy that provides services to a target population unique to the needs of the healthcare services required by the patient. All Class B pharmacies require a PIC or responsible DMP except for pharmaceutical administration facilities and methadone clinics. Examples of a Class B pharmacy[~~ies~~] include:

(a) closed door;

(b) hospital clinic pharmacy;

(c) methadone clinic[s];

(d) nuclear;

(e) branch;

(f) hospice facility pharmacy;

(g) veterinarian pharmaceutical facility;

(h) pharmaceutical administration facility; [~~and~~]

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

(j) [~~A retail pharmacy that prepares sterile products does not require a separate license as a Class B pharmacy.~~]dispensing medical practitioner clinic pharmacy.

(3) A Class C pharmacy includes a pharmacy[~~ies located in Utah~~] that [~~are~~]is involved in:

(a) manufacturing;

(b) producing;

(c) wholesaling;

(d) distributing; and

(e) reverse distributing.

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

(5) A Class E pharmacy [~~includes those pharmacies that do~~]does not require a PIC and includes:

(a) analytical laboratory;

(b) animal control;

(c) durable medical equipment provider;

(d) human clinical investigational drug research facility; [~~and~~]

(e) medical gas provider[~~.~~]; and

(f) animal narcotic detection training facility.

(6) All pharmacy licenses will be converted to the appropriate classification by the Division as

identified in Section 58-17b-302.

(7) Each Class A and each Class B pharmacy required to have a PIC or responsible DMP shall have one PIC or responsible DMP who is employed on a full-time basis as defined by the employer, who acts as a PIC for one pharmacy. However, the PIC may be the PIC of more than one Class A or Class B pharmacy, if the additional Class A or Class B pharmacies are not open to provide pharmacy services simultaneously.

(8) [~~The~~]A PIC or responsible DMP shall comply with the provisions of Section R156-17b-603.

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

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

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

(a) current admission in a College of Pharmacy accredited by the ACPE by written verification from the Dean of the College;

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

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

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

(a) accredited by ASHP; or

(b) conducted by:

(i) the National Pharmacy Technician Association;

(ii) Pharmacy Technicians University; or

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

(c) meets the following standards:

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

(ii) written protocols and guidelines for the teaching pharmacist outlining the utilization and supervision of pharmacy technician[~~s in training~~] trainees that address:

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

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

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

(a) Unless otherwise approved under Subsection (4), [A]an individual who fails to apply for and obtain a pharmacy technician license within the two-year time frame[~~ or within six months after completion of a pharmacy technician training program, whichever comes first:~~

[~~(i) is no longer eligible for employment as a technician-in-training and shall work in the pharmacy only as supportive personnel; and~~

~~(ii)~~]shall repeat a pharmacy technician training program in its entirety if the individual pursues licensure as a pharmacy technician.

(5)(a) Pharmacy technician training programs that received Division approval on or before

April 30, 2014 are exempt from satisfying standards established in Subsection R156-17b-303a(3) for students enrolled on or before December 31, 2018.

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

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

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

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

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

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

[~~(a) is currently licensed and in good standing in another state and has not had any adverse action taken on that license;~~]

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

([~~c~~]b) has passed and maintained current PTCB or ExCPT certification.

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

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

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

(i) At least 1,740 hours of practice supervised by a pharmacy preceptor shall be obtained in Utah or another state or territory of the United States, or a combination of both according to the Accreditation Council for Pharmacy Education (ACPE), Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree Guidelines Version 2.0 Effective February 14, 2011, which is hereby incorporated by reference.

(ii) Introductory pharmacy practice experiences (IPPE) shall account for not less than 300 hours over the first three professional years.

(iii) A minimum of 150 hours shall be balanced between community pharmacy and institutional health system settings.

(iv) Advanced pharmacy practice experiences (APPE) shall include at least 1,440 hours (i.e., 36 weeks) during the last academic year and after all IPPE requirements are completed.

(v) Required experiences shall:

(A) include primary, acute, chronic, and preventive care among patients of all ages; and

(B) develop pharmacist-delivered patient care competencies in the community pharmacy, hospital or health-system pharmacy, ambulatory care, inpatient/acute care, and general medicine settings.

(vi) Internship hours completed in another state or territory of the United States shall be accepted based on the approval of the hours by the pharmacy board in the jurisdiction where the

hours were obtained.

(vii) Evidence of completed internship hours shall be documented to the Division by the pharmacy intern at the time application is made for a Utah pharmacist license.

(viii) Pharmacy interns participating in internships may be credited no more than 50 hours per week of internship experience.

(ix) No credit will be awarded for didactic experience.

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

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

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

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

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

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

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

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

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

~~[(4) Applicants taking the NAPLEX or MPJE examination shall pass the exams within six months from the date of the Division's approval for the applicant to take the exam. If the applicant does not pass the required exam within six months, the pending license application shall be denied.]~~

([~~5~~]4) In accordance with Subsection 58-17b-305(1)(g), an applicant applying for licensure as a pharmacy technician shall pass the PTCB or ExCPT with a passing score as established by the certifying body. The certificate shall exhibit a valid date and that the certification is active.

([~~6~~]5) A graduate of a foreign pharmacy school shall obtain a passing score on the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination.

~~**[R156-17b-310. Exemption from Licensure - Dispensing of Cosmetic, Injectable Weight Loss, or Cancer Drug Treatment Regimen Drugs.**~~

~~(1) A cosmetic drug that can be dispensed by a prescribing practitioner or optometrist in accordance with Subsection 58-17b-309 is limited to Latisse.~~

~~(2) An injectable weight loss drug that can be dispensed by a prescribing practitioner in accordance with Subsection 58-17b-309 is limited to human chorionic gonadotropin.~~

~~(3) A cancer drug treatment regimen that can be dispensed by a prescribing practitioner or an individual employed by the prescribing practitioner in accordance with Subsection 58-17b-309.5(1) and (2) means a prescription drug used to treat cancer, manage its symptoms, or provide continuity of care for a cancer patient.~~

~~(a) A prescribing practitioner who chooses to dispense prescription medications shall disclose to the patient that the cancer drug treatment regimen may be obtained from a pharmacy unaffiliated with the prescribing practitioner and offer to the patient the opportunity to consult with a pharmacist of the patient's choosing if the patient desires patient counseling.~~

~~(b) Practitioners are required to document this interaction by keeping a signature log of all~~

patients who have received this written information. These records are required to be kept for a period of five years and shall be readily available for inspection.

(4) A prescribing practitioner who chooses to dispense prescription medications shall meet the standards set forth in R156-17b-603 through R156-17b-605 and R156-17b-609 through R156-17b-611; however, a prescribing practitioner is not required to employ a pharmacist in charge.

(5) In accordance with Subsections 58-17b-309(4)(c) and 58-17b-309.5(2)(b)(viii), a prescribing practitioner or optometrist who chooses to dispense a cosmetic drug, a prescribing practitioner who chooses to dispense an injectable weight loss drug, as listed in Subsections (1) and (2), or a prescribing practitioner or the prescribing practitioner's employee who chooses to dispense drugs used to treat cancer, manage its symptoms, or provide continuity of care for a cancer patient to the prescribing practitioner's or optometrist's patients shall have a label securely affixed to the container indicating the following minimum information:

(a) the name, address and telephone number of the prescribing practitioner or optometrist prescribing and dispensing the drug;

(b) the serial number of the prescription as assigned by the dispensing prescribing practitioner or optometrist;

(c) the filling date of the prescription or its last dispensing date;

(d) the name of the patient;

(e) the directions for use and cautionary statements, if any, which are contained in the prescription order or are needed;

(f) the trade, generic or chemical name, amount dispensed and the strength of dosage form; and

(g) the beyond use date.

(6) A prescribing practitioner or optometrist who chooses to dispense a cosmetic drug, or a prescribing practitioner who chooses to dispense an injectable weight loss drug, as listed in Subsections (1) and (2), or a prescribing practitioner or the prescribing practitioner's employee who chooses to dispense drugs used to treat cancer, manage its symptoms, or provide continuity of care for a cancer patient shall keep inventory records for each drug dispensed pursuant to R156-17b-605 and a prescription dispensing medication profile for each patient receiving a drug dispensed by the prescribing practitioner or optometrist pursuant to R156-17b-609. Those records shall be made available to the Division upon request by the Division.

(a) The general requirements for an inventory of drugs dispensed by a prescribing practitioner, the prescribing practitioner's employee, or optometrist include:

(i) the prescribing practitioner or optometrist shall be responsible for taking all required inventories, but may delegate the performance of taking the inventory to another person;

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

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

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

(v) the initial inventory shall be completed within three working days of the date on which the prescribing practitioner or optometrist begins to dispense a drug under Sections 58-17b-309 and 58-17b-309.5; and

(vi) the annual inventory shall be within 12 months following the inventory date of each year and may be taken within four days of the specified inventory date and shall include all stocks including out-of-date drugs.

(b) A prescription dispensing medication profile shall be maintained for every patient receiving a drug that is dispensed by a prescribing practitioner or optometrist in accordance with Sections 58-17b-309 and 58-17b-309.5 for a period of at least one year from the date of the most recent prescription fill or refill. The medication profile shall be kept as part of the patient's medical record and include, as a minimum, the following information:

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

(ii) patient history where significant, including known allergies and drug reactions; and

(iii) a list of drugs being dispensed including:

(A) name of prescription drug;

(B) strength of prescription drug;

(C) quantity dispensed;

(D) prescription drug lot number and name of manufacturer;

(E) date of filling or refilling;

(F) charge for the prescription drug as dispensed to the patient;

(G) any additional comments relevant to the patient's drug use; and

(H) documentation that patient counseling was provided in accordance with Subsection (7).

(7) A prescribing practitioner or optometrist who is dispensing a cosmetic drug or injectable weight loss drug listed in Subsections (1) and (2) in accordance with Subsection 58-17b-309(4)(c), or a prescribing practitioner or the prescribing practitioner's employee who chooses to dispense drugs used to treat cancer, manage its symptoms, or provide continuity of care for a cancer patient in accordance with Section 58-17b-309.5, shall include the following elements when providing patient counseling:

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

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

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

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

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

(f) techniques for self-monitoring drug therapy;

(g) proper storage;

(h) prescription refill information;

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

(j) prescribing practitioner or optometrist 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.

(8) In accordance with Subsection 58-17b-309(4)(c), the medication storage standards that shall be maintained by a prescribing practitioner or optometrist who dispenses a drug under Subsections (1) and (2), or a prescribing practitioner or the prescribing practitioner's employee who chooses to dispense drugs used to treat cancer, manage its symptoms, or provide continuity of care for a cancer patient in accordance with Section 58-17b-309.5, provides that the storage space shall be:

(a) kept in an area that is well lighted, well ventilated, clean and sanitary;

(b) equipped to permit the orderly storage of prescription drugs in a manner to permit clear identification, separation and easy retrieval of products and an environment necessary to maintain the integrity of the drug inventory;

(c) equipped with a security system to permit detection of entry at all times when the prescribing practitioner's or optometrist's office or clinic is closed;

(d) at a temperature which is maintained within a range compatible with the proper storage of drugs; and

~~(e) securely locked with only the prescribing practitioner or optometrist having access when the prescribing practitioner's or optometrist's office or clinic is closed.~~

~~(9) In accordance with Subsections 58-17b-309(5) and 58-17b-309.5(1)(b), if a cosmetic drug or a weight loss drug listed in Subsections (1) and (2), or a drug used to treat cancer, manage its symptoms, or provide continuity of care for a cancer patient requires reconstitution or compounding to prepare the drug for administration, the prescribing practitioner or optometrist shall follow the USP-NF 797 standards for sterile compounding.~~

~~(10) In accordance with Subsection 58-17b-309(5), factors that shall be considered by licensing boards when determining if a drug may be dispensed by a prescribing practitioner, the prescribing practitioner's employee or optometrist, include whether:~~

~~(a)(i) the drug has FDA approval;~~

~~(ii)(A) is prescribed and dispensed for the conditions or indication for which the drug was approved to treat; or~~

~~(B) the prescribing practitioner or optometrist takes full responsibility for prescribing and dispensing a drug for off-label use;~~

~~(b) the drug has been approved for self administration by the FDA;~~

~~(c) the stability of the drug is adequate for the supply being dispensed; and~~

~~(d) the drug can be safely dispensed by a prescribing practitioner or optometrist.~~

~~(11) Standards for reporting to the Utah Controlled Substance Database shall be the same standards as set forth in the Utah Controlled Substance Database Act, Title 58, Chapter 37f, and the Utah Controlled Substance Database Act Rule, R156-37f.~~]

R156-17b-401. Disciplinary Proceedings.

(1) An individual licensed as a pharmacy intern who is currently under disciplinary action and qualifies for licensure as a pharmacist may be issued a pharmacist license under the same restrictions as the pharmacy intern license.

(2) A pharmacist, pharmacy intern, [~~or~~]pharmacy technician, pharmacy technician trainee, or DMP whose license or registration is suspended under Subsection 58-17b-701(6) may petition the Division at any time that he or she can demonstrate the ability to resume competent practice.

R156-17b-402. Administrative Penalties.

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

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

initial offense: $500 - $2,000

subsequent offense(s): $5,000

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

initial offense: $100 - $1,000

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

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

initial offense: $500 - $2,000

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

(4) conducting or transacting business under a name which contains as part of that name the words drugstore, pharmacy, drugs, medicine store, medicines, drug shop, apothecary, prescriptions or any other term having a similar meaning or in any manner advertising otherwise describing or

referring to the place of the conducted business or profession when not licensed to do so, in violation of Subsection 58-17b-501(3)(b):

initial offense: $500 - $2,000

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

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

initial offense: $1,000 - $5,000

subsequent offense(s): $10,000

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

initial offense: $100 - $500

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

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

initial offense: $500 - $2,000

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

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

initial offense: $500 - $2,000

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

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

initial offense: $500 - $2,000

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

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

initial offense: $500 - $1,000

subsequent offense(s): $1,500 - $5,000

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

initial offense: $500 - $2,000

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

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

initial offense: $1,000 - $5,000

subsequent offense(s): $10,000

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

initial offense: $100 - $500

subsequent offense(s): $1,000 - $2,5000

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

initial offense: $500 - $2,000

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

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

initial offense:$2,500 - $5,000

subsequent offense(s):$5,500 - $10,000

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

initial offense: $1,000 - $5,000

subsequent offense(s): $10,000

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

initial offense: $500 - $2,000

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

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

initial offense: $1,000 - $5,000

subsequent offense(s): $10,000

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

initial offense: $500 - $2,000

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

(20) violating Federal Title II, PL 91, Controlled Substances Act or Title 58, Chapter 37, Utah Controlled Substances Act, or rules and regulations adopted under either act, in violation of Subsection 58-17b-502(7):

initial offense: $500 - $2,000

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

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

initial offense: $100 - $500

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

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

initial offense: $500 - $2,000

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

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

initial offense: $100 - $500

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

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

initial offense: $100 - $500

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

(25) failing to report to the Division any adverse action taken by another licensing jurisdiction,

government agency, law enforcement agency or court, in violation of Subsection 58-17b-502(12):
initial offense: $100 - $500
subsequent offense(s): $500 - $1,000
(26) preparing a prescription drug, including compounding a prescription drug, for sale to another pharmacist or pharmaceutical facility, in violation of Subsection 58-17b-502(13):
initial offense: $100 - $500
subsequent offense(s): $500 - $1,000
(27) preparing a prescription drug in a dosage form which is regularly and commonly available from a manufacturer in quantities and strengths prescribed by a practitioner, in violation of Subsection 58-17b-502(14):
initial offense: $500 - $1,000
subsequent offense(s): $2,500 - $5,000
(28) violating any ethical code provision of the American Pharmaceutical Association Code of Ethics for Pharmacists, October 27, 1994, in violation of Subsection R156-17b-502(1):
initial offense: $250 - $500
subsequent offense(s): $2,000 - $10,000
(29) failing to comply with USP-NF Chapter 795 guidelines, in violation of Subsection R156-17b-502(2):
initial offense: $250 - $500
subsequent offense(s): $500 - $750
(30) failing to comply with USP-NF Chapter 797 guidelines, in violation of Subsection R156-17b-502(2):
initial offense: $500 - $2,000
subsequent offense(s) $2,500 - $10,000
(31) failing to comply with the continuing education requirements set forth in this rule, in violation of Subsection R156-17b-502(3):
initial offense: $100 - $500
subsequent offense(s): $500 - $1,000
(32) failing to provide the Division with a current mailing address within 10 days following any change of address, in violation of Subsection R156-17b-502(4):
initial offense: $50 - $100
subsequent offense(s): $200 - $300
(33) defaulting on a student loan, in violation of Subsection R156-17b-502(5):
initial offense: $100 - $200
subsequent offense(s): $200 - $500
(34) failing to abide by all applicable federal and state law regarding the practice of pharmacy, in violation of Subsection R156-17b-502(6):
initial offense: $500 - $1,000
subsequent offense(s): $2,000 - $10,000
(35) failing to comply with administrative inspections, in violation of Subsection R156-17b-502(7):
initial offense: $500 - $2,000
subsequent offense(s): $2,000 - $10,000
(36) failing to return a self-inspection report according to the deadline established by the Division, or providing false information on a self-inspection report, in violation of Subsection R156-17b-502(8):
initial offense: $100 - $250
subsequent offense(s): $300 - $500
(37) violating the laws and rules regulating operating standards in a pharmacy discovered

upon inspection by the Division, in violation of Subsection R156-17b-502(9):
initial violation: $50 - $100
failure to comply within determined time: $250 - $500
subsequent violations: $250 - $500
failure to comply within established time: $750 - $1,000
(38) abandoning a pharmacy and/or leaving drugs accessible to the public, in violation of Subsection R156-17b-502(10):
initial offense: $500 - $2,000
subsequent offense(s): $2,000 - $10,000
(39) failing to identify license classification when communicating by any means, in violation of Subsection R156-17b-502(11):
initial offense: $100 - $500
subsequent offense(s): $500 - $1,000
(40) failing to maintain an appropriate ratio of personnel, in violation of Subsection R156-17b-502(12):
Pharmacist initial offense: $100 - $250
Pharmacist subsequent offense(s): $500 - $2,500
Pharmacy initial offense: $250 - $1,000
Pharmacy subsequent offense(s): $500 - $5,000
(41) allowing any unauthorized persons in the pharmacy, in violation of Subsection R156-17b-502(13):
Pharmacist initial offense: $50 - $100
Pharmacist subsequent offense(s): $250 - $500
Pharmacy initial offense: $250 - $500
Pharmacy subsequent offense(s): $1,000 - $2,000
(42) failing to offer to counsel any person receiving a prescription medication, in violation of Subsection R156-17b-502(14):
Pharmacy personnel initial offense: $500 - $2,500
Pharmacy personnel subsequent offense(s): $5,000 - $10,000
Pharmacy: $2,000 per occurrence
(43) failing to pay an administrative fine within the time designated by the Division, in violation of Subsection R156-17b-502(15):
Double the original penalty amount up to $10,000
(44) failing to comply with the PIC standards as established in Section R156-17b-603, in violation of Subsection R156-17b-502(16):
initial offense: $500 - $2,000
subsequent offense(s) $2,000 - $10,000
(45) failing to take appropriate steps to avoid or resolve identified drug therapy management problems as referenced in Subsection R156-17b-611(3), in violation of Subsection R156-17b-502(17):
initial offense: $500 - $2,500
subsequent offense: $5,000 - $10,000
(46) dispensing a medication that has been discontinued by the FDA, in violation of Subsection R156-17b-502(18):
initial offense: $100 - $500
subsequent offense: $200 - $1,000
(47) failing to keep or report accurate records of training hours, in violation of Subsection R156-17b-502(19):
initial offense: $100 - $500

subsequent offense: $200 - $1,000

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

initial offense: $100 - $500

subsequent offense: $200 - $1,000

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

initial offense: $500 - $2,000

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

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

Pharmacist initial offense: $100 - $300

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

Pharmacy initial offense: $250 - $500

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

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

initial offense: $500 - $2,000

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

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

initial offense: $500 - $2,000

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

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

initial offense: $500 - $1,000

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

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

initial offense: $500 - $1,000

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

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

initial offense: $100 - $2,000

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

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

initial offense: $500 - $2,000

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

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

initial offense: $500 - $2,000

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

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

initial offense: $100 - $2,000
subsequent offense(s): $2,000 - $10,000
(59) violating or aiding or abetting any other person to violate any generally accepted professional or ethical standard, in violation of Subsection 58-1-501(2)(b):
initial offense: $500 - $2,000
subsequent offense(s): $2,000 - $10,000
(60) engaging in conduct that results in conviction of, or a plea of nolo contendere, or a plea of guilty or nolo contendere held in abeyance to a crime, in violation of Subsection 58-1-501(2)(c):
initial offense: $500 - $2,000
subsequent offense(s): $2,000 - $10,000
(61) engaging in conduct that results in disciplinary action by any other jurisdiction or regulatory authority, that if the conduct had occurred in this state, would constitute grounds for denial of licensure or disciplinary action, in violation of Subsection 58-1-501(2)(d):
initial offense: $100 - $500
subsequent offense(s): $200 - $1,000
(62) engaging in conduct, including the use of intoxicants, drugs, or similar chemicals, to the extent that the conduct does or may impair the ability to safely engage in practice as a pharmacist, pharmacy intern, [~~or~~]pharmacy technician, or pharmacy technician trainee, in violation of Subsection 58-1-501(2)(e):
initial offense: $100 - $500
subsequent offense(s): $200 - $1,000
(63) practicing or attempting to practice as a pharmacist, pharmacy intern, [~~or~~]pharmacy technician, or pharmacy technician trainee when physically or mentally unfit to do so, in violation of Subsection 58-1-501(2)(f):
initial offense: $100 - $500
subsequent offense(s): $200 - $1,000
(64) practicing or attempting to practice as a pharmacist, pharmacy intern, [~~or~~]pharmacy technician, or pharmacy technician trainee through gross incompetence, gross negligence or a pattern of incompetency or negligence, in violation of Subsection 58-1-501(2)(g):
initial offense: $500 - $2,000
subsequent offense(s): $2,000 - $10,000
(65) practicing or attempting to practice as a pharmacist, pharmacy intern, [~~or~~]pharmacy technician, or pharmacy technician trainee by any form of action or communication which is false, misleading, deceptive or fraudulent, in violation of Subsection 58-1-501(2)(h):
initial offense: $100 - $500
subsequent offense(s): $200 - $1,000
(66) practicing or attempting to practice as a pharmacist, pharmacy intern, [~~or~~]pharmacy technician, or pharmacy technician trainee beyond the individual's scope of competency, abilities or education, in violation of Subsection 58-1-501(2)(i):
initial offense: $100 - $500
subsequent offense(s): $200 - $1,000
(67) practicing or attempting to practice as a pharmacist, pharmacy intern, [~~or~~]pharmacy technician, or pharmacy technician trainee beyond the scope of licensure, in violation of Subsection 58-1-501(2)(j):
initial offense: $100 - $500
subsequent offense(s): $200 - $1,000
(68) verbally, physically or mentally abusing or exploiting any person through conduct connected with the licensee's practice, in violation of Subsection 58-1-501(2)(k):
initial offense: $100 - $1,000

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

(69) acting as a supervisor without meeting the qualification requirements for that position as defined by statute or rule, in violation of Subsection 58-1-501(2)(l):

initial offense: $100 - $500

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

(70) violating a provision of Section 58-1-501.5, in violation of Subsection 58-1-501(2)(n):

initial offense: $500 - $2,000

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

(71) surrendering licensure to any other licensing or regulatory authority having jurisdiction over the licensee or applicant in the same occupation or profession while an investigation or inquiry into allegations of unprofessional or unlawful conduct is in progress or after a charging document has been filed against the applicant or licensee alleging unprofessional or unlawful conduct, in violation of Subsection R156-1-501(1):

initial offense: $500 - $2,000

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

(72) practicing a regulated occupation or profession in, through, or with a limited liability company that has omitted the words, "limited company," "limited liability company," or the abbreviation "L.C." or "L.L.C." in the commercial use of the name of the limited liability company, in violation of Subsection R156-1-501 (2):

initial offense: $500 - $2,000

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

(73) practicing a regulated occupation or profession in, through, or with a limited partnership that has omitted the words, "limited partnership," "limited," or the abbreviation "L.P." or "L.td." in the commercial use of the name of the limited partnership, in violation of Subsection R156-1-501(3):

initial offense: $500 - $2,000

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

(74) practicing a regulated occupation or profession in, through, or with a professional corporation that has omitted the words "professional corporation" or the abbreviation "P.C." in the commercial use of the name of the professional corporation, in violation of Subsection R156-1-501(4):

initial offense: $500 - $2,000

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

(75) using a capitalized DBA (doing-business-as name) that has not been properly registered with the Division of Corporations and with the Division of Occupational and Professional Licensing, in violation of Subsection R156-1-501(5):

initial offense: $500 - $2,000

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

(76) failing, as a prescribing practitioner, to follow the "Model Policy for the Use of Controlled Substances for the Treatment of Pain," May 2004, established by the Federation of State Medical Boards of the United States, Inc., which is hereby adopted and incorporated by reference, in violation of R156-1-501(6):

initial offense: $500 - $2,000

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

(77) engaging in prohibited acts as defined in Section 58-37-8, in violation of Section 58-37-8:

initial offense: $1,000 - $5,000

subsequent offense(s) $5,000 - $10,000

(78) self-prescribing or self-administering by a licensee of any Schedule II or Schedule III controlled substance which is not prescribed by another practitioner having authority to prescribe the drug, in violation of Subsection R156-37-502(1)(a):

initial offense: $500 - $2,000

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

(79) prescribing or administering a controlled substance for a condition that the licensee is not licensed or competent to treat, in violation of Subsection R156-37-502(1)(b):

initial offense: $500 - $2,000

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

(80) violating any federal or state law relating to controlled substances, in violation of Subsection R156-37-502(2):

initial offense: $500 - $2,000

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

(81) failing to deliver to the Division all controlled substance certificates issued by the Division, to the Division, upon an action which revokes, suspends, or limits the license, in violation of R156-37-502(3):

initial offense: $500 - $2,000

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

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

initial offense: $500 - $2,000

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

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

initial offense: $500 - $2,000

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

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

initial offense: $500 - $2,000

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

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

initial offense: $500 - $2,000

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

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

initial offense: $500 - $2,000

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

(87) any other conduct which constitutes unprofessional or unlawful conduct:

initial offense: $100 - $500

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

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

initial offense: $500 - $2,000

subsequent offense: $2,500 - $10,000

R156-17b-502. Unprofessional Conduct.

"Unprofessional conduct" includes:

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

(2) if applicable, failing to comply with the USP-NF Chapters 795 and 797;

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

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

(5) defaulting on a student loan;

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

(7) failing to comply with administrative inspections;

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

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

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

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

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

(13) allowing any unauthorized persons in the pharmacy;

(14) failing to offer to counsel any person receiving a prescription medication;

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

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

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

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

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

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

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

(22) requiring a pharmacy, [~~PIC, or any other~~]pharmacist, or DMP to operate the pharmacy or allow operation of the pharmacy with a ratio of supervising pharmacist or DMP to other pharmacy[~~technician/pharmacy intern/support~~]personnel which, under the circumstances of the particular practice setting, results in, or reasonably would be expected to result in, an unreasonable risk of harm to public health, safety, and welfare;

(23) failing to update the Division within seven calendar days of any change in the email address designated for use in self-audits or pharmacy alerts; [~~and~~]

(24) effective November 30, 2014, failing to comply with prescription container label standards established in USP-NF Chapter 17[~~.~~]; and

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

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

In accordance with Subsection 58-17b-102(5[~~3~~]6), practice as a licensed pharmacy technician

is defined as follows:

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

(a) receiving written prescriptions;

(b) taking refill orders;

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

(d) preparing labels;

(e) retrieving medications from inventory;

(f) counting and pouring into containers;

(g) placing medications into patient storage containers;

(h) affixing labels;

(i) compounding;

(j) counseling for over-the-counter drugs and dietary supplements under the direction of the supervising pharmacist as referenced in Subsection 58-17b-102(5[~~3~~]6);

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

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

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

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

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

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

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

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

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

(B) process for supervising technicians who check medications;

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

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

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

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

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

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

([~~2~~]3) The pharmacy technician shall not receive new prescriptions or medication orders as described in Subsection 58-17b-102(5[~~3~~]6)(b)(iv), clarify prescriptions or medication orders nor perform drug utilization reviews. A new prescription, as used in Subsection 58-17b-102(5[~~3~~]6)(b)(iv), does not include authorization of a refill of a legend drug.

([~~3~~]4) Pharmacy technicians shall have general supervision by a pharmacist in accordance with Subsection R156-17b-603([~~2~~]3)(s).

([4]5) No more than one pharmacy technician[~~-in-training~~] trainee per shift shall practice in a pharmacy. A pharmacy technician[~~-in-training~~] trainee shall practice only under the direct supervision of a pharmacist.

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

A pharmacy intern may provide services including the practice of pharmacy under the supervision of an approved preceptor, as defined in Subsection 58-17b-102([~~48~~]50), provided the pharmacy intern met the criteria as established in Subsection R156-17b-306.

R156-17b-603. Operating Standards - Pharmacist-[~~i~~]In-[~~c~~]Charge or Responsible DMP.

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

(2) In accordance with Subsections 58-17b-103(1) and 58-17b-601(1), a [~~secure~~]unique email address shall be established by the PIC[~~-or responsible party~~], responsible DMP, or responsible party for the pharmacy to be used for self-audits or pharmacy alerts initiated by the Division. The PIC, responsible DMP, or responsible party shall notify the Division of the pharmacy's [~~secure-~~]email address [~~initially as follows:~~

~~(a) at the September 30, 2013 renewal for all licensees; and~~

~~(b) thereafter, on~~]in the initial application for licensure.

(3) The duties of the PIC or responsible DMP shall include:

(a) assuring that a pharmacist[~~s~~],[~~-and~~] pharmacy intern[~~s~~], DMP, or DMP designee dispenses drugs or devices, including:

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

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

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

[~~(c) assuring that a pharmacist, pharmacy intern or pharmacy technician communicates to the patient or the patient's agent information about the prescription drug or device or non-prescription products;~~]

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

([e]d) assuring that a reasonable effort is made to obtain, record and maintain patient medication records;

([f]e) education and training of pharmacy [~~technicians~~]personnel;

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

([~~h~~]g) disposal and distribution of drugs from the pharmacy;

([i]h) bulk compounding of drugs;

([j]i) storage of all materials, including drugs, chemicals and biologicals;

([k]j) maintenance of records of all transactions of the pharmacy necessary to maintain

accurate control over and accountability for all pharmaceutical materials required by applicable state and federal laws and regulations;

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

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

([~~n~~]m) legal operation of the pharmacy including meeting all inspection and other requirements of all state and federal laws, rules and regulations governing the practice of pharmacy;

([~~p~~]o) implementation of an ongoing quality assurance program that monitors performance of the automated pharmacy system, which is evidenced by written policies and procedures developed for pharmaceutical care;

([~~o~~]n) if permitted to use an [~~assuring that any~~]automated pharmacy system for dispensing purposes:

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

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

([~~q~~]p) assuring that all relevant information is submitted to the Controlled Substance Database in the appropriate format and in a timely manner;

([~~r~~]q) assuring that all pharmacy personnel [~~working in the pharmacy~~]have the appropriate licensure;

([~~s~~]q) assuring that no pharmacy [~~or pharmacist~~]operates [~~the pharmacy or allows operation of the pharmacy~~]with a ratio of pharmacist or DMP to other pharmacy [~~technician/pharmacy intern/support~~] personnel which, under the circumstances of the particular practice setting, results in, or reasonably would be expected to result in, an unreasonable risk of harm to public health, safety, and welfare;

([~~t~~]s) assuring that the PIC or responsible DMP assigned to the pharmacy is recorded with the Division and that the Division is notified of a change in PIC or responsible DMP within 30 days of the change; and

([~~u~~]t) assuring with regard to the [~~secure~~]unique email address used for self-audits and pharmacy alerts that:

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

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

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

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

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

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

(b) the anticipated date of closing;

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

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

(2) If the pharmacy dispenses prescription drug orders, post a closing notice sign in a

conspicuous place in the front of the prescription department and at all public entrance doors to the pharmacy. Such closing notice shall contain the following information:

(a) the date of closing; and

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

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

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

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

(4) If the pharmacy dispenses prescription drug orders:

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

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

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

(a) the actual date of closing;

(b) the license issued to the pharmacy;

(c) a statement attesting:

(i) that an inventory as specified in Subsection R156-17b-605(5) has been conducted; and

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

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

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

(a) DEA registration certificate;

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

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

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

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

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

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

(1) All out of date legend drugs and controlled substances shall be removed from the

inventory at regular intervals and in correlation to the beyond use date imprinted on the label.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) a pharmacy that changes ownership shall take an inventory of all legend drugs and

controlled substances including out-of-date drugs and drugs in automated pharmacy systems on the date of the change of ownership;

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

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

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

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

R156-17b-606. Operating Standards - Approved Preceptor.

In accordance with Subsection 58-17b-601(1), the operating standards for a pharmacist acting as a preceptor include:

(1) meeting the following criteria:

(a) hold a Utah pharmacist license that is active and in good standing;

(b) document engaging in active practice as a licensed pharmacist for not less than [~~two~~]one year[s] in any jurisdiction;

(c) not be under any sanction which, when considered by the Division and Board, would be of such a nature that the best interests of the intern and the public would not be served;

(d) provide direct, on-site supervision to:

(i) no more than two pharmacy interns during a working shift except as provided in Subsection (ii);

(ii) up to five pharmacy interns at public-health outreach programs such as informational health fairs, chronic disease state screening and education programs, and immunization clinics, provided:

(A) the totality of the circumstances are safe and appropriate according to generally recognized industry standards of practice; and

(B) the preceptor has obtained written approval from the pharmacy interns' schools of pharmacy for the intern's participation; and

(e) refer to the intern training guidelines as outlined in the Pharmacy Coordinating Council of Utah Internship Competencies, October 12, 2004, as information about a range of best practices for training interns;

(2) maintaining adequate records to document the number of internship hours completed by the intern and evaluating the quality of the intern's performance during the internship;

(3) completing the preceptor section of a Utah Pharmacy Intern Experience Affidavit found in the application packet at the conclusion of the preceptor/intern relationship regardless of the time or circumstances under which that relationship is concluded; and

(4) being responsible for the intern's actions related to the practice of pharmacy while practicing as a pharmacy intern under supervision.

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

(1) In accordance with Subsection 58-17b-102(66)(a), supportive personnel may assist in any tasks not related to drug preparation or processing including:

(a) stock ordering and restocking;

(b) cashiering;

(c) billing;
(d) filing;
(e) receiving a written prescription and delivering it to the pharmacist, pharmacy intern, [~~or~~]pharmacy technician, pharmacy technician trainee, DMP, or DMP designee;
(f) housekeeping; and
(g) delivering a pre-filled prescription to a patient.
(2) Supportive personnel shall not enter information into a patient prescription profile or accept verbal refill information.
(3) In accordance with Subsection 58-17b-102([~~66~~]69)(b)[~~, the supervision of supportive personnel is defined as follows:~~
(~~a~~)]all supportive personnel shall be under the supervision of a licensed pharmacist or DMP.[~~;~~ ~~and~~
(~~b) t~~]The licensed pharmacist or DMP shall be present in the area where the person being supervised is performing services and shall be immediately available to assist the person being supervised in the services being performed except for the delivery of prefilled prescriptions as provided in Subsection (1)(g) above.
(4) In accordance with Subsection 58-17b-601(1), a pharmacist, pharmacy intern, [~~or~~] pharmacy technician, pharmacy technician trainee, DMP, or DMP designee whose license has been revoked or is suspended shall not be allowed to provide any support services in a pharmacy.

R156-17b-608. Common Carrier Delivery.
A pharmacy that employs the United States Postal Service or other common carrier to deliver a filled prescription directly to a patient shall, under the direction of the [~~pharmacist-in-charge~~]PIC, responsible DMP, or other responsible employee:
(1) use adequate storage or shipping containers and shipping processes to ensure drug stability and potency. The shipping processes shall include the use of appropriate packaging material and devices, according to the recommendations of the manufacturer or the United States Pharmacopeia Chapter 1079, in order to ensure that the drug is kept at appropriate storage temperatures throughout the delivery process to maintain the integrity of the medication;
(2) use shipping containers that are sealed in a manner to detect evidence of opening or tampering;
(3) develop and implement policies and procedures to ensure accountability, safe delivery, and compliance with temperature requirements. The policies and procedures shall address when drugs do not arrive at their destination in a timely manner or when there is evidence that the integrity of a drug was compromised during shipment. In these instances, the pharmacy shall make provisions for the replacement of the drugs;
(4) provide for an electronic, telephonic, or written communication mechanism for a pharmacy[~~pharmacist, or a pharmacy intern working under the direct supervision of a pharmacist,~~] to offer counseling to the patient as defined in Section 58-17b-613 and there shall be documentation of such counseling; and
(5) provide information to the patient indicating what the patient should do if the integrity of the packaging or drug was compromised during shipment.

R156-17b-609. Operating Standards - Medication Profile System.
In accordance with Subsections 58-17b-601(1) and 58-17b-604(1), the following operating standards shall apply with respect to medication profile systems:
(1) Patient profiles, once established, shall be maintained by a [~~pharmacist in a~~]pharmacy dispensing to patients on a recurring basis for a minimum of one year from the date of the most recent prescription filled or refilled; except that a hospital pharmacy may delete the patient profile for

an inpatient upon discharge if a record of prescriptions is maintained as a part of the hospital record.

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

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

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

(i) name of prescription drug;

(ii) strength of prescription drug;

(iii) quantity dispensed;

(iv) date of filling or refilling;

(v) charge for the prescription drug as dispensed to the patient; and

(c) any additional comments relevant to the patient's drug use.

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

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

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

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

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

(3) Based upon the [~~pharmacist's or pharmacy intern's~~]professional judgment of the pharmacist, pharmacy intern, or DMP, patient counseling may be discussed to include the following elements:

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

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

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

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

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

(f) techniques for self-monitoring drug therapy;

(g) proper storage;

(h) prescription refill information;

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

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

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

(4) The offer to counsel shall be documented and said documentation shall be available to the Division. These records shall be maintained for a period of five years and be available for inspection within 7-10 business days.

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

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

(a) the information specified in Subsection (1) of this section shall be delivered with the dispensed prescription in writing;

(b) if prescriptions are routinely delivered outside the area covered by the pharmacy's local telephone service, the pharmacist shall place on the prescription container or on a separate sheet

delivered with the prescription container, the telephone number of the pharmacy and the statement "Written information about this prescription has been provided for you. Please read this information before you take this medication. If you have questions concerning this prescription, a pharmacist is available during normal business hours to answer these questions."; and

(c) written information provided in Subsection (8)(b) of this section shall be in the form of patient information leaflets similar to USP-NF patient information monographs or equivalent information.

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

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

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

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

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

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

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

(5) Prescriptions for legend drugs having a remaining authorization for refill may be transferred by the pharmacist,[~~or~~] pharmacy intern, or DMP at the pharmacy holding the prescription to a pharmacist,[~~or~~] pharmacy intern or DMP at another pharmacy upon the authorization of the patient to whom the prescription was issued or electronically as authorized under Subsection R156-17b-613(9). The transferring pharmacist,[~~or~~] pharmacy intern, or DMP and receiving pharmacist,[~~or~~] pharmacy intern, or DMP shall act diligently to ensure that the total number of authorized refills is not exceeded. The following additional terms apply to such a transfer:

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

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

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

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

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

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

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

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

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

(D) the name and address of the pharmacy and the name of the pharmacist,[~~or~~] pharmacy

intern, or DMP to which such prescription is transferred; and

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

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

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

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

(7) Refills may be dispensed only in accordance with the prescriber's authorization as indicated on the original prescription drug order;

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

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

(10) Refills of prescription drug orders for controlled substances shall be done in accordance with Subsection 58-37-6(7)(f).

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

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

(b) either:

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

(ii) the pharmacist or DMP is unable to contact the practitioner after a reasonable effort, the effort should be documented and said documentation should be available to the Division;

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

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

(e) the pharmacist or DMP informs the practitioner of the emergency refill at the earliest reasonable time;

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

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

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

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

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

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

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

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

(14) In accordance with Subsection 58-37-6(7)(e), a prescription may not be written, issued, filled, or dispensed for a Schedule I controlled substance unless:

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

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

(15) Effective November 30, 2014, prescription container labels shall comply with standards established in USP-NF Chapter 17.

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

In accordance with Subsections 58-17b-102([~~27~~]29) through ([~~28~~]30), 58-17b-602(1), R156-82, and R156-1, prescription orders may be issued by electronic means of communication according to the following standards:

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

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

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

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

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

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

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

(c) the pharmacist or DMP shall exercise professional judgment regarding the accuracy and authenticity of the transmitted prescription. Practitioners or their agents transmitting medication orders using electronic equipment are to provide voice verification when requested by the pharmacist receiving the medication order. The pharmacist or DMP is responsible for assuring that each electronically transferred prescription order is valid and shall authenticate a prescription order issued by a prescribing practitioner which has been transmitted to the dispensing pharmacy before filling it, whenever there is a question;

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

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

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

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

pharmacy only.

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

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

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

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

(9) A prescription order for a legend drug or controlled substance in Schedule III through V may be transferred up to the maximum refills permitted by law or by the prescriber by electronic transmission providing the pharmacies share a real-time, on-line database provided that:

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

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

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

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

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

(iv) the date and time of the transfer.

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

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

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

(b) if engaged in prepackaging, the dispensing area, if any, shall have a sink with hot and cold culinary water separate and apart from any restroom facilities. This does not apply to clean rooms where sterile products are prepared. Clean rooms should not have sinks or floor drains that expose the area to an open sewer. All required equipment shall be clean and in good operating condition;

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

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

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

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

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

(ii) provide notice of unauthorized entry to an individual[~~who is able to respond quickly and reasonably assess the entry and resolve the matter~~]; and

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

(2) The temperature of the pharmacy shall be maintained within a range compatible with the proper storage of drugs. If a refrigerator or freezer is necessary to properly store drugs at the

pharmacy,[~~T~~]the pharmacy shall keep a daily written or electronic log of the temperature of the refrigerator [~~and~~]or freezer on days of operation for not less than three years[~~ shall be maintained within a range compatible with the proper storage of drugs requiring refrigeration or freezing~~].

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

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

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

(c) bulk active ingredients shall:

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

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

(d) a master worksheet sheet shall be [~~developed and~~]approved by a pharmacist or DMP for each batch of sterile or non-sterile pharmaceuticals to be prepared. Once approved, a duplicate of the master worksheet sheet shall be used as the preparation worksheet sheet from which each batch is prepared and on which all documentation for that batch occurs. The master worksheet sheet may be stored electronically and shall contain at a minimum:

(i) the formula;

(ii) the components;

(iii) the compounding directions;

(iv) a sample label information;

(v) evaluation and testing requirements;

(vi) sterilization methods, if applicable;

(vii) specific equipment used during preparation such as specific compounding device; and

(viii) storage requirements;

(e) a preparation worksheet sheet for each batch of sterile or non-sterile pharmaceuticals shall document the following:

(i) identity of all solutions and ingredients and their corresponding amounts, concentrations, or volumes;

(ii) manufacturer lot number for each component;

(iii) component manufacturer or suitable identifying number;

(iv) container specifications (e.g. syringe, pump cassette);

(v) unique lot or control number assigned to batch;

(vi) beyond use date of batch prepared products;

(vii) date of preparation;

(viii) name, initials or electronic signature of the person or persons involved in the preparation;

(ix) names, initials or electronic signature of the responsible pharmacist or DMP;

(x) end-product evaluation and testing specifications, if applicable; and

(xi) comparison of actual yield to anticipated yield, when appropriate;

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

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

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

(iii) quantity;

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

(v) appropriate ancillary instructions, such as storage instructions or cautionary statements,

including cytotoxic warning labels where appropriate; and

(vi) device-specific instructions, where appropriate;

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

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

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

(B) manufacturer recommendations; and

(C) reliable, published research;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(5) The facility shall maintain a current list of licensed employees involved in the practice of pharmacy at the facility. The list shall include individual licensee names, license classifications, license numbers, and license expiration dates. The list shall be readily retrievable upon inspection by Division and may be maintained in paper or electronic form. [~~The facility shall post the license of the facility and the license or a copy of the license of each pharmacist, pharmacy intern and pharmacy technician who is employed in the facility, but may not post the license of any pharmacist, pharmacy intern or pharmacy technician not actually employed in the facility.~~]

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

(7) A pharmacy shall not dispense a prescription drug or device to a patient unless a pharmacist or DMP is physically present and immediately available in the facility. [~~If the pharmacy is located within a larger facility such as a grocery or department store, and a licensed Utah pharmacist is not immediately available in the facility, the pharmacy shall not remain open to pharmacy patients and shall be locked in such a way as to bar entry to the public or any non-pharmacy personnel. All pharmacies located within a larger facility shall be locked and enclosed in such a way as to bar entry by the public or any non-pharmacy personnel when the pharmacy is closed.~~]

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

(9) The facility or parent company shall maintain a [~~permanent log~~]record for not less than 5 years of the initials or identification codes which identify each dispensing pharmacist or DMP by name. The initials or identification code shall be unique to ensure that each pharmacist or DMP can be identified; therefore identical initials or identification codes shall not be used.

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) The parties performing or contracting for centralized prescription processing or filling services shall maintain a policy and procedures manual and documentation that implementation is occurring in a manner that shall be made available to the Division upon inspection and that includes the following:

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

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

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

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

(e) the maintenance of 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.

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

In accordance with Subsections 58-17b-102([44]47) and 58-17b-601(1), the operating standards for Class C pharmacies designated as pharmaceutical wholesaler/distributor and pharmaceutical manufacturer licensees includes the following:

(1) Every pharmaceutical wholesaler or manufacturer that engages in the wholesale distribution and manufacturing of drugs or medical devices [~~located in this state~~]shall be licensed by the Division. A separate license shall be obtained for each separate location engaged in the distribution or manufacturing of prescription drugs. Business names cannot be identical to the name used by another unrelated wholesaler licensed to purchase drugs and devices in Utah.

(2) Manufacturers distributing only their own FDA-approved prescription drugs or co-licensed product shall satisfy this requirement by registering their establishment with the Federal Food and Drug Administration pursuant to 21 CFR Part 207 and submitting the information required by 21 CFR Part 205, including any amendments thereto, to the Division.

(3) An applicant for licensure as a pharmaceutical wholesale distributor shall provide the following minimum information:

(a) All trade or business names used by the licensee (including "doing business as" and "formerly known as");

(b) Name of the owner and operator of the license as follows:

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

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

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

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

(v) if a limited liability company, the name of each member, social security number of each member, the name of each manager, the name of the limited liability company and federal employer identification number, and the name of the state in which the limited liability company was organized; and

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

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

(a) is at least 21 years of age;

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

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

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

(e) is physically present at the facility during regular business hours, except when the absence

of the designated representative is authorized, including but not limited to, sick leave and vacation leave; and

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

(5) The licensee shall provide the name, business address, and telephone number of a person to serve as the designated representative for each facility of the pharmaceutical wholesaler that engages in the distribution of drugs or devices.

[~~(6) Each facility that engages in pharmaceutical wholesale distribution and manufacturing facilities shall undergo an inspection by the Division for the purposes of inspecting the pharmaceutical wholesale distribution or manufacturing operation prior to initial licensure and periodically thereafter with a schedule to be determined by the Division.~~]

(7) All pharmaceutical wholesalers and manufacturer shall publicly display or have readily available all licenses and the most recent inspection report administered by the Division.

(8) All Class C pharmacies shall:

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

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

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

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

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

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

(9) Each facility used for wholesale drug distribution or manufacturing of prescription drugs shall:

(a) be secure from unauthorized entry;

(b) limit access from the outside to a minimum in conformance with local building codes, life and safety codes and control access to persons to ensure unauthorized entry is not made;

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

(d) be well lighted on the outside perimeter;

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

(f) be equipped with security measures, systems and procedures necessary to provide reasonable security against theft and diversion of prescription drugs or alteration or tampering with computers and records pertaining to prescription drugs or prescription drug precursors.

(10) Each facility shall provide the storage of prescription drugs, prescription drug precursors, and prescription drug devices in accordance with the following:

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

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

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

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

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

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

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

(iii) transaction dates;

(iv) name of the prescription drug;

(v) dosage form and strength of the prescription drug;

(vi) size of the container;

(vii) number of containers;

(viii) lot number of the prescription drug;

(ix) name of the manufacturer of the finished dose form; and

(x) National Drug Code (NDC) number.

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

(12) Each facility shall comply with the following requirements:

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

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

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

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

(c) each outgoing shipment shall be carefully inspected for identity of the prescription drug products or devices and to ensure that there is no delivery of prescription drugs or devices that have

been damaged in storage or held under improper conditions:

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

(ii) returns of expired, damaged, recalled, or otherwise non-saleable prescription drugs shall be distributed by the receiving pharmaceutical wholesale distributor only to the original manufacturer or a third party returns processor that is licensed as a pharmaceutical wholesale distributor under this chapter;

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

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

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

(14) Prescription drugs furnished by a manufacturer or pharmaceutical wholesaler shall be delivered only to the business address of a person described in Subsections R156-17b-102(16)(c) and R156-17b-615(13), or to the premises listed on the license, or to an authorized person or agent of the licensee at the premises of the manufacturer or pharmaceutical wholesaler if the identity and authority of the authorized agent is properly established.

(15) Each facility shall establish and maintain records of all transactions regarding the receipt and distribution or other disposition of prescription drugs and prescription drug precursors and shall make inventories of prescription drugs and prescription drug precursors and required records available for inspection by authorized representatives of the federal, state and local law enforcement agencies in accordance with the following:

(a) there shall be a record of the source of the prescription drugs or prescription drug precursors to include the name and principal address of the seller or transferor and the address of the location from which the drugs were shipped;

(b) there shall be a record of the identity and quantity of the prescription drug or prescription drug precursor received, manufactured, distributed or shipped or otherwise disposed of by specific product and strength;

(c) there shall be a record of the dates of receipt and distribution or other disposal of any product;

(d) there shall be a record of the identity of persons to whom distribution is made to include name and principal address of the receiver and the address of the location to which the products were shipped;

(e) inventories of prescription drugs and prescription drug precursors shall be made available during regular business hours to authorized representatives of federal, state and local law enforcement authorities;

(f) required records shall be made available for inspection during regular business hours to authorized representatives of federal, state and local law enforcement authorities and such records shall be maintained for a period of two years following disposition of the products; and

(g) records that are maintained on site or immediately retrievable from computer or other

electronic means shall be made readily available for authorized inspection during the retention period; or if records are stored at another location, they shall be made available within two working days after request by an authorized law enforcement authority during the two year period of retention.

(16) Each facility shall establish, maintain and adhere to written policies and procedures which shall be followed for the receipt, security, storage, inventory, manufacturing, distribution or other disposal of prescription drugs or prescription drug precursors, including policies and procedures for identifying, recording and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. In addition, the policies shall include the following:

(a) a procedure whereby the oldest approved stock of a prescription drug or precursor product is distributed or used first with a provision for deviation from the requirement if such deviation is temporary and appropriate;

(b) a procedure to be followed for handling recalls and withdrawals of prescription drugs adequate to deal with recalls and withdrawals due to:

(i) any action initiated at the request of the FDA or other federal, state or local law enforcement or other authorized administrative or regulatory agency;

(ii) any voluntary action to remove defective or potentially defective drugs from the market; or

(iii) any action undertaken to promote public health, safety or welfare by replacement of existing product with an improved product or new package design;

(c) a procedure to prepare for, protect against or handle any crisis that affects security or operation of any facility in the event of strike, fire, flood or other natural disaster or other situations of local, state or national emergency;

(d) a procedure to ensure that any outdated prescription drugs or prescription drug precursors shall be segregated from other drugs or precursors and either returned to the manufacturer, other appropriate party or appropriately destroyed;

(e) a procedure for providing for documentation of the disposition of outdated, adulterated or otherwise unsafe prescription drugs or prescription drug precursors and the maintenance of that documentation available for inspection by authorized federal, state or local authorities for a period of five years after disposition of the product;

(f) a procedure for identifying, investigating and reporting significant drug inventory discrepancies (involving counterfeit drugs suspected of being counterfeit, contraband, or suspect of being contraband) and reporting of such discrepancies within three (3) business days to the Division and/or appropriate federal or state agency upon discovery of such discrepancies; and

(g) a procedure for reporting criminal or suspected criminal activities involving the inventory of drugs and devices to the Division, FDA and if applicable, Drug Enforcement Administration (DEA), within three (3) business days.

(17) Each facility shall establish, maintain and make available for inspection by authorized federal, state and local law enforcement authorities, lists of all officers, directors, managers and other persons in charge which lists shall include a description of their duties and a summary of their background and qualifications.

(18) Each facility shall comply with laws including:

(a) operating within applicable federal, state and local laws and regulations;

(b) permitting the state licensing authority and authorized federal, state and local law enforcement officials, upon presentation of proper credentials, to enter and inspect their premises and delivery vehicles and to audit their records and written operating policies and procedures, at reasonable times and in a reasonable manner, to the extent authorized by law; and

(c) obtaining a controlled substance license from the Division and registering with the Drug Enforcement Administration (DEA) if they engage in distribution or manufacturing of controlled substances and shall comply with all federal, state and local regulations applicable to the distribution or manufacturing of controlled substances.

(19) Each facility shall be subject to and shall abide by applicable federal, state and local laws that relate to the salvaging or reprocessing of prescription drug products.

(20) [~~A person who is engaged in the wholesale distribution or manufacturing of prescription drugs but does not have a facility located within Utah in which prescription drugs are located, stored, distributed or manufactured is exempt from Utah licensure as a Class C pharmacy, if said person is currently licensed and in good standing in each state of the United States in which that person has a facility engaged in distribution or manufacturing of prescription drugs entered into interstate commerce.~~

~~(21) No facility located at the same address shall be dually licensed as both a Class C pharmacy and any other classification of Class A or B pharmacy~~]A Class C pharmacy shall not be located in the same building as a separately licensed Class A, B, D, or E pharmacy unless the two pharmacies are located in different suites as recognized by the United States Postal Service. Two Class C pharmacies may be located at the same address in the same suite if the pharmacies:

(a) are under the same ownership;

(b) have processes and systems for separating and securing all aspects of the operation;

(c) have traceability with a clear audit trail that distinguishes a pharmacy's purchases and distributions.[~~Nothing within this section prevents a facility from obtaining licensure for a secondary address which operates separate and apart from any other facility upon obtaining proper licensure.~~]

R156-17b-616. Operating Standards - Class D Pharmacy - Out of State Mail Order Pharmacies.

(1) In accordance with Subsections 58-1-301(3) and 58-17b-306(2), an application for licensure as a Class D pharmacy shall include:

(a) a pharmacy care protocol that includes the operating standards established in Subsections R156-17b-610(1) and (8) and R156-17b-612(1) through (4);

(b) a copy of the pharmacist's license for the PIC; and

(c) a copy of the most recent state inspection or NABP inspection completed as part of the NABP Verified Pharmacy Program (VPP) showing the status of compliance with the laws and regulations for physical facility, records and operations.

(2) An out of state mail order pharmacy that compounds [~~must~~]shall follow the USP-NF Chapter 795 Compounding of non-sterile preparations and Chapter 797 Compounding of sterile preparations.

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

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

(a) the identity of the supervisor or director;

(b) a detailed plan of care;

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

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

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

R156-17b-617c. Class E Pharmacy Operating Standards – Animal Control or Animal Narcotic Detection Training.

(1) In accordance with Section 58-17b-302 and Subsection 58-17b-601(1), an animal control or animal narcotic detection training facility shall:

(a) maintain for immediate retrieval a perpetual inventory of all drugs including controlled substances that are purchased, stored, processed and administered;

(b) maintain for immediate retrieval a current list of authorized employees and their training

with regards to the handling and use of legend drugs and/or controlled substances in relation to euthanasia, [~~or~~]immobilization, or narcotic detection training of animals;

(c) maintain, for immediate retrieval documentation of all required materials pertaining to legitimate animal scientific drug research, guidance policy and other relevant documentation from the agency's Institutional Review Board, if applicable;

(d) maintain stocks of legend drugs and controlled substances to the smallest quantity needed for efficient operation to conduct animal euthanasia, [~~or~~]immobilization, or narcotic detection training purposes;

(e) maintain all legend drugs and controlled substances in an area within a building having perimeter security which limits access during working hours, provides adequate security after working hours, and has the following security controls:

(i) a permanently secured safe or steel cabinet substantially constructed with self-closing and self-locking doors employing either multiple position combination or key lock type locking mechanisms; and

(ii) requisite key control, combination limitations, and change procedures;

(f) have a responsible party who is the only person authorized to purchase and reconcile legend drugs and controlled substances and is responsible for the inventory of the animal control or animal narcotic detection training facility pharmacy;

(g) ensure that only defined and approved individuals pursuant to the written facility protocol have access to legend drugs and controlled substances; and

(h) develop and maintain written policies and procedures for immediate retrieval which include the following:

(i) the type of activity conducted with regards to legend drugs and/or controlled substances;

(ii) how medications are purchased, inventoried, prepared and used in relation to euthanasia, [~~or~~]immobilization, or narcotic detection training of animals;

(iii) the type, form and quantity of legend drugs and/or controlled substances handled;

(iv) the type of safe or equally secure enclosures or other storage system used for the storage and retrieval of legend drugs and/or controlled substances;

(v) security measures in place to protect against theft or loss of legend drugs and controlled substances;

(vi) adequate supervision of employees having access to manufacturing and storage areas;

(vii) maintenance of records documenting the initial and ongoing training of authorized employees with regard to all applicable protocols;

(viii) maintenance of records documenting all approved and trained authorized employees who may have access to the legend drugs and controlled substances; and

(ix) procedures for allowing the presence of business guests, visitors, maintenance personnel, and non-employee service personnel.

~~[(2) In accordance with Section 58-37-6 and Subsection R156-37-305(1), individuals employed by an agency of the State or any of its political subdivisions who are specifically authorized in writing by their employer to possess specified controlled substances in specified reasonable and necessary quantities for the purpose of euthanasia, or immobilization, or narcotic detection training upon of animals, shall be exempt from having a controlled substance license if the employing agency or jurisdiction has obtained a controlled substance license and a DEA registration number, and uses the controlled substances according to a written protocol in performing animal euthanasia, or]immobilization or narcotic detection training.]~~

R156-17b-617f. Class E Pharmacy Operating Standards – Medical Gas Provider

In accordance with Section 58-17b-302 and Subsection 58-17b-601(1), a medical gas facility shall:

(a) develop standard operating policy and procedures manual;
(b) conduct training and maintain evidence of employee training programs and completion certificates;
(c) maintain documentation and records of all transactions to include:
(i) batch production records
(ii) certificates of analysis
(iii) dates of calibration of gauges;
(d) provide adequate space for orderly placement of equipment and finished product;
(e) maintain gas tanks securely;
(f) designate return and quarantine areas for separation of products;
(g) label all products;
(h) fill cylinders without using adapters; and
(i) comply with all FDA standards and requirements.

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

(1) In accordance with Section 58-17b-614, except for changes in ownership caused by a change in the stockholders in corporations which are publicly listed and whose stock is publicly traded, a licensed pharmaceutical facility shall make application for a new license and receive approval from the Division no later than ten business days prior to any of the following proposed changes:
(a) location or address, except for a reassignment of a new address by the United States Postal Service that does not involve any change of location;
(b) name, except for a doing-business-as (DBA) name change that is properly registered with the Division of Corporations and filed with the Division of Occupational and Professional Licensing; or
(c) ownership[~~.~~] when one of the following occurs;
(i) a change in entity type; or
(ii) a sell or transfer of 51% or more of an entity's ownership or membership interest to another individual or entity.
(2) Upon approval of the change in location, name, or ownership, and the issuance of a new license, the original license shall be surrendered to the Division.
([~~b~~]3) Upon approval of the name change, the original licenses shall be surrendered to the Division.

R156-17b-622. Standards - Dispensing Training Program

(1) In accordance with Subsection R156-17b-102 (17-), a formal or on-the-job dispensing training program completed by a DMP designee is one which covers the following topics to the extent that the topics are relevant and current to the DMP practice where the DMP designee is employed:
(a) role of the DMP designee;
(b) laws affecting prescription drug dispensing;
(c) pharmacology including the identification of drugs by trade and generic names, and therapeutic classifications;
(d) pharmaceutical terminology, abbreviations and symbols;
(e) pharmaceutical calculations;
(f) drug packaging and labeling;
(g) computer applications in the pharmacy;
(h) sterile and non-sterile compounding;
(i) medication errors and safety;
(j) prescription and order entry and fill process;
(k) pharmacy inventory management; and

(l) pharmacy billing and reimbursement.

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

(a) name of individual trained;

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

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

(d) training completion date.

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

(1) A cosmetic drug that may be dispensed by a DMP in accordance with Section 58-17b-803 is limited to Latisse.

(2) An injectable weight loss drug that may be dispensed by a DMP in accordance with Section 58-17b-803 is limited to human chorionic gonadotropin.

R156-17b-624. Operating Standards. Repackaged or Compounded Prescription Drugs - Sale to a Practitioner for Office Use.

Pursuant to Section 58-17b-624, a pharmacy may repackage or compound a prescription drug for sale to a practitioner for office use provided that it is in compliance with all applicable federal and state laws and regulations regarding the practice of pharmacy, including, but not limited to the Food, Drug, and Cosmetic Act [21 U.S.C.A § 301 et seq.].

(6)

R156. Commerce, Occupational and Professional Licensing.
R156-37. Utah Controlled Substances Act Rule.

R156-37-301. License Classifications - Restrictions.

(1) Consistent with the provisions of law, the Division may issue a controlled substance license to manufacture, produce, distribute, dispense, prescribe, obtain, administer, analyze, or conduct research with controlled substances in Schedules I, II, III, IV, or V to qualified persons. Licenses shall be issued to qualified persons in the following categories:

(a) pharmacist;
(b) optometrist;
(c) podiatric physician;
(d) dentist;
(e) osteopathic physician and surgeon;
(f) physician and surgeon;
(g) physician assistant;
(h) veterinarian;
(i) advanced practice registered nurse or advanced practice registered nurse-certified registered nurse anesthetist;
(j) certified nurse midwife;
(k) naturopathic physician;
(l) Class A pharmacy-retail operations located in Utah;
(m) Class B pharmacy located in Utah providing services to a target population unique to the needs of the healthcare services required by the patient, including:
(i) closed door;
(ii) hospital clinic pharmacy;
(iii) methadone clinic[~~s~~];
(iv) nuclear;
(v) branch;
(vi) hospice facility pharmacy;
(vii) veterinarian pharmaceutical facility;
(viii) pharmaceutical administration facility; [~~and~~]
(ix) sterile product preparation facility[~~.~~]; and
(x) dispensing medical practitioner clinic pharmacy;
(n) Class C pharmacy [~~located in Utah~~]engaged in:
(i) manufacturing;
(ii) producing;
(iii) wholesaling; [~~and~~]
(iv) distributing[~~.~~]; and
(v) reverse distributing.
(o) Class D Out-of-state mail order pharmacies.
(p) Class E pharmacy including:
(i) medical gases provider[~~s~~]; [~~and~~]
(ii) analytical laboratory[~~ies.~~];
(iii) animal control;
(iv) human clinical investigational drug research facility; and
(v) animal narcotic detection training facility.
(q) Utah Department of Corrections for the conduct of execution by the administration of lethal injection under its statutory authority and in accordance with its policies and procedures.

(2) A license may be restricted to the extent determined by the Division, in collaboration with appropriate licensing boards, that a restriction is necessary to protect the public health, safety or welfare, or the welfare of the licensee. A person receiving a restricted license shall manufacture, produce, obtain, distribute, dispense, prescribe, administer, analyze, or conduct research with controlled substances only to the extent of the terms and conditions under which the restricted license is issued by the Division.

R156-37-302. Qualifications for Licensure - Application Requirements.

(1) An applicant for a controlled substance license shall:

(a) submit an application in a form as prescribed by the Division; and

(b) shall pay the required fee as established by the Division under the provisions of Section 63J-1-504.

(2) Any person seeking a controlled substance license shall[~~:~~

~~(a)~~]be currently licensed by the state in the appropriate professional license classification as listed in R156-37-301 and shall maintain that license classification as current at all times while holding a controlled substance license[~~; or~~

~~(b) be engaged in the following activities which require the administration of a controlled substance but do not require licensure under Subsection (a):~~

~~(i) animal capture for transport or relocation as an employee or under contract with a state or federal government agency; or~~

~~(ii) other activity approved by the Division in collaboration with the appropriate board~~].

(3) The Division and the reviewing board may request from the applicant information which is reasonable and necessary to permit an evaluation of the applicant's:

(a) qualifications to engage in practice with controlled substances; and

(b) the public interest in the issuance of a controlled substance license to the applicant.

(4) To determine if an applicant is qualified for licensure, the Division may assign the application to a qualified and appropriate licensing board for review and recommendation to the Division with respect to issuance of a license.

~~**[R156-37-304. Qualifications for Licensure - Examinations.**~~

~~Each applicant for a controlled substance license shall be required to pass an examination administered at the direction of the Division on the subject of controlled substance laws.~~]

R156-37-305. Exemption from Licensure - Animal [~~Euthanasia~~]Control, Animal Narcotic Detection Training[~~and~~], Law Enforcement Personnel, and University Research.

In accordance with Subsection 58-37-6(2)(d), the following persons are exempt from licensure under Title 58, Chapter 37:

(1) Individuals employed by an agency of the State or any of its political subdivisions, who are specifically authorized in writing by the state agency or the political subdivision to possess specified controlled substances in specified reasonable and necessary quantities for the purpose of [~~euthanasia upon~~] animal[~~s~~] control or animal narcotic detection training, shall be exempt from having a controlled substance license if the agency or jurisdiction employing that individual has obtained a controlled substance license, a DEA registration number, and uses the controlled substances according to a written protocol in performing animal [~~euthanasia~~]control or animal narcotic detection training.

(2) Law enforcement agencies and their sworn personnel are exempt from the licensing requirements of the Controlled Substance Act to the extent their official duties require them to possess controlled substances; they act within the scope of their enforcement responsibilities; they

maintain accurate records of controlled substances which come into their possession; and they maintain an effective audit trail. Nothing herein shall authorize law enforcement personnel to purchase or possess controlled substances for administration to animals unless the purchase or possession is in accordance with a duly issued controlled substance license.

(3) Individuals and entities engaged in research using pharmaceuticals as defined in Subsection 58-17b-102 (65) within a research facility as defined in Subsection R156-17b-102 (48).

(4) Individuals employed by a business engaged in narcotic detection training of animals for law enforcement use if the business employing that individual has obtained a controlled substance license, a DEA registration number, and uses the controlled substances according to a written protocol in performing narcotic detection training.

R156-37-502. Unprofessional Conduct.

"Unprofessional conduct" includes:

(1) a licensee with authority to prescribe or administer controlled substances:

(a) prescribing or administering to himself any Schedule II or III controlled substance which is not lawfully prescribed by another licensed practitioner having authority to prescribe the drug;

(b) prescribing or administering a controlled substance for a condition he is not licensed or competent to treat;

(2) violating any federal or state law relating to controlled substances;

(3) failing to deliver to the Division all controlled substance license certificates issued by the Division to the Division upon an action which revokes, suspends or limits the license;

(4) failing to maintain controls over controlled substances which would be considered by a prudent practitioner to be effective against diversion, theft, or shortage of controlled substances;

(5) being unable to account for shortages of any controlled substance inventory for which the licensee has responsibility;

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

(7) refusing to make available for inspection controlled substance stock, inventory, and records as required under this rule or other law regulating controlled substances and controlled substance records;

(8) failing to submit controlled substance prescription information to the database manager after being notified in writing to do so.

R156-37-602. Records.

(1) Records of purchase, distribution, dispensing, prescribing, and administration of controlled substances shall be kept according to state and federal law. Prescribing practitioners shall keep accurate records reflecting the examination, evaluation and treatment of all patients. Patient medical records shall accurately reflect the prescription or administration of controlled substances in the treatment of the patient, the purpose for which the controlled substance is utilized and information upon which the diagnosis is based. Practitioners shall keep records apart from patient records of each controlled substance purchased, and with respect to each controlled substance, its disposition, whether by administration or any other means, date of disposition, to whom given and the quantity given.

(2) Any licensee who experiences any shortage or theft of controlled substances shall immediately file the appropriate forms with the Drug Enforcement Administration, with a copy to the

Division directed to the attention of the Investigation Bureau. He shall also report the incident to the local law enforcement agency.

(3) All records required by federal and state laws or rules must be maintained by the licensee for a period of five years. If a licensee should sell or transfer ownership of his files in anyway, those files shall be maintained separately from other records of the new owner.

(4) Prescription records may be maintained electronically so long as they are readily retrievable and comply with 21 CFR 1304.04.[~~:~~

~~(a) the original of each prescription, including telephone prescriptions, is maintained in a physical file and contains all of the information required by federal and state law; and~~

~~(b) an automated data processing system is used for the storage and immediate retrieval of refill information for prescription orders for controlled substances in Schedule III and IV, in accordance with federal guidelines.~~]

(5) All records relating to Schedule II controlled substances received, purchased, administered or dispensed by the practitioner shall be maintained separately from all other records of the pharmacy or practice.

(6) All records relating to Schedules III, IV and V controlled substances received, purchased, administered or dispensed by the practitioner shall be maintained separately from all other records of the pharmacy or practice.

R156-37-603. Restrictions Upon the Prescription, Dispensing and Administration of Controlled Substances.

(1) A practitioner may prescribe or administer the Schedule II controlled substance cocaine hydrochloride only as a topical anesthetic for mucous membranes in surgical situations in which it is properly indicated and as local anesthetic for the repair of facial and pediatric lacerations when the controlled substance is mixed and dispensed by a registered pharmacist in the proper formulation and dosage.

(2) A practitioner shall not prescribe or administer a controlled substance without taking into account the drug's potential for abuse, the possibility the drug may lead to dependence, the possibility the patient will obtain the drug for a nontherapeutic use or to distribute to others, and the possibility of an illicit market for the drug.

[~~(3) When writing a prescription for a controlled substance, each prescription shall contain only one controlled substance per prescription form and no other legend drug or prescription item shall be included on that form.~~]

([4]3) In accordance with Subsection 58-37-6(7)(f)(v)(D), unless the prescriber determines there is a valid medical reason to allow an earlier dispensing date, the dispensing date of a second or third prescription shall be no less than 30 days from the dispensing date of the previous prescription, to allow for receipt of the subsequent prescription before the previous prescription runs out.

([~~5~~]4) If a practitioner fails to document his intentions relative to refills of controlled substances in Schedules III through V on a prescription form, it shall mean no refills are authorized. No refill is permitted on a prescription for a Schedule II controlled substance.

([~~6~~]5) Refills of controlled substance prescriptions shall be permitted for the period from the original date of the prescription as follows:

(a) Schedules III and IV for six months from the original date of the prescription; and

(b) Schedule V for one year from the original date of the prescription.

([~~7~~]6) No refill may be dispensed until such time has passed since the date of the last dispensing that 80% of the medication in the previous dispensing should have been consumed if taken according to the prescriber's instruction.

([~~8~~]7) No prescription for a controlled substance shall be issued or dispensed without specific instructions from the prescriber on how and when the drug is to be used.

([~~9~~]8) Refills after expiration of the original prescription term requires the issuance of a new prescription by the prescribing practitioner.

([~~10~~]9) Each prescription for a controlled substance and the number of refills authorized shall be documented in the patient records by the prescribing practitioner.

([~~11~~]10) A practitioner shall not prescribe or administer a Schedule II controlled stimulant for any purpose except:

(a) the treatment of narcolepsy as confirmed by neurological evaluation;

(b) the treatment of abnormal behavioral syndrome, attention deficit disorder, hyperkinetic syndrome, or related disorders;

(c) the treatment of drug-induced brain dysfunction;

(d) the differential diagnostic psychiatric evaluation of depression;

(e) the treatment of depression shown to be refractory to other therapeutic modalities, including pharmacologic approaches, such as tricyclic antidepressants or MAO inhibitors;

(f) in the terminal stages of disease, as adjunctive therapy in the treatment of chronic severe pain or chronic severe pain accompanied by depression;

(g) the clinical investigation of the effects of the drugs, in which case the practitioner shall submit to the Division a written investigative protocol for its review and approval before the investigation has begun. The investigation shall be conducted in strict compliance with the investigative protocol, and the practitioner shall, within 60 days following the conclusion of the investigation, submit to the Division a written report detailing the findings and conclusions of the investigation; or

(h) in treatment of depression associated with medical illness after due consideration of other therapeutic modalities.

([~~12~~]11) A practitioner may prescribe, dispense or administer a Schedule II controlled stimulant when properly indicated for any purpose listed in Subsection (11), provided that all of the following conditions are met:

(a) before initiating treatment utilizing a Schedule II controlled stimulant, the practitioner obtains an appropriate history and physical examination, and rules out the existence of any recognized contraindications to the use of the controlled substance to be utilized;

(b) the practitioner shall not prescribe, dispense or administer any Schedule II controlled stimulant when he knows or has reason to believe that a recognized contraindication to its use exists;

(c) the practitioner shall not prescribe, dispense or administer any Schedule II controlled stimulant in the treatment of a patient who he knows or should know is pregnant; and

(d) the practitioner shall not initiate or shall discontinue prescribing, dispensing or administering all Schedule II controlled stimulants immediately upon ascertaining or having reason to believe that the patient has consumed or disposed of any controlled stimulant other than in compliance with the treating practitioner's directions.

R156-37-606. Disposal of Controlled Substances.

(1) Any disposal of controlled substances by licensees shall[:]

[~~(a)~~] be consistent with the provisions of 1307.21 of the Code of Federal Regulations[~~; or~~

~~(b) require the authorization of the Division after submission to the Division to the attention of Chief Investigator of a detailed listing of the controlled substances and the quantity of each. Disposal shall be conducted in the presence of one of its investigators or a Division authorized agent as is specifically instructed by the Division in its written authorization~~].

(2) Records of disposal of controlled substances shall be maintained and made available on request to the Division or its agents for inspection for a period of five years.

KEY: controlled substances, licensing
Date of Enactment or Last Substantive Amendment: January 8, 2013
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R156. Commerce, Occupational and Professional Licensing.
R156-37f. Controlled Substance Database Act Rule.

R156-37f-102. Definitions.

In addition to the definitions in Sections 58-17b-102, 58-37-2 and 58-37f-102, as used in this chapter:

(1) "ASAP" means the American Society for Automation in Pharmacy system.

(2) "DEA" means Drug Enforcement Administration.

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

(4) "NCPDP" means National Council for Prescription Drug Programs.

(5) "NDC" means National Drug Code.

(6) "Positive identification" means:

(a) one of following photo identifications issued by a foreign or domestic government:

(i) driver's license;

(ii) non-driver identification card;

(iii) passport;

(iv) military identification; or

(v) concealed weapons permit; or

(b) only in cases when the individual does not have government-issued identification may the pharmacist request alternative evidence of the individual's identity as deemed appropriate by the pharmacist as long as the pharmacist documents in a prescription record a description of how the individual was positively identified.

([~~6~~]7) "Research facility" means a facility in which research takes place that has policies and procedures describing such research.

([~~7~~]8) "Rx" means a prescription.

KEY: controlled substance database, licensing
Date of Enactment or Last Substantive Amendment: November 21, 2013
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