

Pharmacy Board Report  
2013

#1

	January-Aug 2013	Sep-13
Administrative Filings	20	3
Criminal Filing/Felony	3	
Letter of Concern	39	3
Cases Received	517	59
Case Assigned	501	48
Closed Cases	528	64
Citations Issued	76	9
Pharmacy Inspections	146	28
Pharmacy Alerts	123	10
Dr. Shopper/Law Enforcement Letters	89	9

**NOTES:**

Whitney Beckstead-Pharmacy Inspector

**Sep-13**

The Division hired Whitney Beckstead as the new Pharmacy Inspector. Ashleigh Ney has been promoted to a Pharmacy Investigator.

Lynn Hooper

Investigator Lynn Hooper attended the National Association of Boards of Pharmacy (NABP)-Sterile Compound Pharmacy Compliance Training in October 2013 at Mount Prospect IL. The training provided excellent insight into completing inspections of compounding pharmacies along with providing information which can be adapted into a Compound Inspection Form.

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**DIVISION OF OCCUPATIONAL AND PROFESSIONAL LICENSING  
PROPOSED RULE OR CHANGE**

**Title of Rule or Section:** R156-17b, Pharmacy Practice Act Rule

**Contact Person:** Richard J. Oborn, Bureau Manager, 801-530-6767, roborn@utah.gov

**Hearing Date and Time (if any):** November 19, 2013

**Date proposed amendments approved by Board/Committee:** September 24, 2013

**Purpose of or reason for the filing:** S.B. 14 and S.B. 194 passed during the 2013 General Legislative Session. S.B. 14 exempted research using pharmaceuticals from licensure to engage in the practice of pharmacy, telepharmacy, or the practice of pharmacy technician. S.B. 194 amended the following: (1) definition of pharmaceutical wholesaler or distributor; (2) definition of the "practice as a licensed pharmacy technician; and (3) pharmacy technician licensure qualifications. Both S.B. 14 and S.B. 194 granted authority to the Division to adopt amendments and this rule filing establishes those amendments. Other amendments are proposed at the request of the Board of Pharmacy.

**Summary of the filing:**

The following rule amendments are made throughout R156-17b: Updating of references, renumbering of paragraphs and minor grammatical changes.

**Section 102:** Subsections (18), (19), and (33) are added due to statutory amendments made in S.B. 194 to the definition of pharmaceutical wholesaler or distributor. These amendments granted the Division authority to define the following terms: "entities under common administrative control," "entities under common ownership," and "other health care facilities." Subsection (42) is added due to statutory amendments made in S.B. 14 to exempt research using pharmaceuticals from licensure to engage in the practice of pharmacy, telepharmacy, or the practice of pharmacy technician. These amendments granted the Division authority to define the term "research facility." In Subsection (47), the term "expiration date" is removed and replaced with "beyond use date" to be consistent with terminology used in federal law.

**Section 105:** Proposed amendment corrects an incorrect citation.

**Section 303a:** Under S.B. 194, pharmacy technician programs no longer require Division approval; however, acceptable programs must meet standards established by Division rule. The proposed standards allow pharmacy technician programs already approved by the Division to continue until January 1, 2016. In order to continue as a pharmacy technician program after January 1, 2016, programs must be accredited or conducted by the American Society of Health System Pharmacists, the National Technician Association or a branch of the Armed Forces of the United States. Under the proposed rule, the Division will continue to approve programs until April 20, 2014.

**Sections 303b and 305:** Proposed amendments correct grammatical errors.

Section 304: Proposed amendments allow the Division to issue a temporary pharmacist license to a student who has not yet graduated but who is in the second year of a pharmacy graduate residency program.

Section 310: Proposed amendment corrects an incorrect citation and clarifies standards relating to when a prescribing practitioner can prescribe and dispense a cancer drug treatment regimen.

Section 402: Proposed amendment adds the word "Subsection" as needed. In Subsection (58), the minimum fine for an initial offense for violating or aiding or abetting any other person to violate any statute, rule, or order regulating pharmacy is reduced to \$100.

Section 502: In Subsection (17), the proposed amendment makes it unprofessional conduct for a pharmacy, pharmacist, or pharmacy technician to fail to adhere to institutional policies and procedures related to technician checking of medications when technician checking is utilized. The passing of S.B. 194 prompted this rule amendment. In Subsection (24), the proposed amendment makes it unprofessional conduct for a pharmacy or pharmacist to fail to comply with prescription container label standards established in USP-NF Chapter 17. Most pharmacies and pharmacists already comply with USP-NF Chapter 17; however, those that currently do not are given until November 30, 2014 to comply.

Section 601: In Subsection (1), the proposed amendments establish when a pharmacy technician is permitted to conduct a final review of a prescribed drug prepared for dispensing. S.B. 194 granted the Division the authority to establish these amendments. Proposed amendments also correct incorrect citations. In Subsections (2) and (3), the operating standards of a pharmacy technician are further clarified and defined.

Section 602: Proposed amendments correct incorrect citations.

Section 603: Proposed amendment corrects a grammatical error.

Section 605: Proposed amendments restructure the inventory requirements to make them consistent with 21 CFR 1304.11 and with how the Division currently interprets requirements.

Section 612: In Subsection (15), proposed amendment requires that prescription container labels comply with standards established in USP-NF Chapter 17.

Section 613: Proposed amendments correct incorrect citations.

Section 614a: The term "expiration date" is removed and replaced with "beyond use date" throughout the section to be consistent with terminology used in federal law. In Subsection (1), proposed amendments clarify that all Class A and B pharmacies are required to comply with general operating standards established in this section. In

Subsection (3), it is clarified that only pharmacies engaged moderate or complex non-sterile or any level of sterile compounding shall be subject to standards established in this subsection. A typographical error is corrected in Subsection (4). Proposed amendments to Subsection (9) clarify that pharmacies may maintain permanent logs of the initials or identification codes which identify each dispensing pharmacist by name at the parent company rather than only at the actual pharmacy where drugs are dispensed. Proposed amendments to Subsection (12) and (13) remove the requirement that pharmacies maintain suppliers' invoices and credit memos for legend drugs.

Sections 615 and 616: Incorrect rule titles and citations are corrected throughout these sections.

Section 617e: A typographical error is corrected in Subsection (2).

**Cost or saving impact of filing (Aggregate Impact):**

**State Budget:** Under amendments to Section 303a, beginning March 31, 2014, the Division will no longer approve individual pharmacy technician training programs. Shifting the responsibility to approve programs from the Division to the American Society of Health System Pharmacists (ASHSP), the National Pharmacy Technician Association, or a branch of the Armed Forces of the United States will result in a small reduction in work for the Division. This is because the Division and Board will no longer be required to review applications for approval of programs. In this case, the cost savings is minimal because the Division currently receives a small number of applications each year.

In Subsection 402 (58), the minimum fine for an initial offense for violating or aiding or abetting any other person to violate any statute, rule, or order regulating pharmacy is reduced to \$100. Reducing this amount will (1) reduce the potential fine charged for this violation; and (2) result in the Division being more likely to issue fines to licensees who violate their disciplinary orders.

The Division will incur minimal costs of approximately \$100 to print and distribute the rule once the proposed amendments are made effective.

Any additional cost impact to the state budget results from statutory amendments and was covered in the fiscal note completed for S.B. 14 and S.B. 194.

**Local Government:** The proposed amendments only apply to pharmacies, pharmacists, pharmacy technicians, pharmacy interns, and applicants for licensure in the pharmacy profession. As a result, the proposed amendments do not apply to local governments.

**Small Business (less than 50 employees):** Amendments to the pharmacy technician education requirement in Section 303a will have cost impact on schools with pharmacy technician programs and pharmacies with pharmacy technician on-the-job training programs. To obtain accreditation from the American Society of Health System

Pharmacists (ASHSP) before January 1, 2016, schools must pay an initial application fee of \$475. To maintain ASHSP accreditation, schools pay an annual assessment fee of anywhere between \$2,200 and \$4,400 depending on the number of training sites they use. Retail chain-based pharmacies that choose to have their own on-the-job training programs will pay a \$10,000 initial application fee to ASHSP. To maintain accreditation, retail chain-based pharmacies pay an \$8,400 annual assessment fee. Smaller pharmacies will direct students to either enroll in a ASHSP accredited school or in the National Pharmacy Technician Association (NPTA) Online Program.

Proposed amendments to Section 601 establish when a pharmacy technician is permitted to conduct a final review of a prescribed drug prepared for dispensing. These amendments will likely result in a cost savings for facilities that decide to allow pharmacy technicians to conduct a final review of a prescribed drug prepared for dispensing. The amount of the cost savings depends on several factors such as the number pharmacy technicians allowed to conduct final reviews at particular pharmacies. Furthermore, amending Subsection (3) to require general supervision rather than direct supervision will likely result in a cost savings for some pharmacies.

In Subsection 612 (15), proposed amendments require that pharmacies create prescription container labels that comply with standards established in USP-NF Chapter 17. Many pharmacies already comply with these standards; however, those that do not must comply by November 30, 2014. The cost impact of this rule amendment to these pharmacies will depend on the degree to which they currently comply with USP-NF Chapter 17.

In Subsection 614a (9), proposed amendments allow pharmacies to maintain suppliers' invoices at a parent company rather than at the actual pharmacy. Furthermore, supplier invoices for legend drugs are no longer required to be maintained. These amendments will likely result in cost savings for some pharmacies but the Division is unable to estimate a cost savings amount due to varying circumstances.

**Other Persons:** Amendments to the pharmacy technician education requirement in Section 303a will have cost impact on some individuals seeking to be trained as pharmacy technicians. Some schools may increase their tuition fees once they are required to obtain ASHSP accreditation and this will result in cost impact to students. The Division is unable to estimate a cost impact amount due to varying circumstances.

Under these amendments, some pharmacies may choose to no longer have an on-the-job training program. Individuals completing on-the-job training programs at these pharmacies will either have to complete the program at a different pharmacy or complete an online program through the National Pharmacy Technician Association (NPTA). If they choose to complete the NPTA online program, tuition is currently \$2,241 for 9 courses.

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issue fines to licensees who violate their disciplinary orders.

**Compliance costs for affected persons (Individual Impact):** Amendments to the pharmacy technician education requirement in Section 303a will have cost impact on some individuals seeking to be trained as pharmacy technicians. Some schools may increase their tuition fees once they are required to obtain ASHSP accreditation and this will result in cost impact to students. The Division is unable to estimate a cost impact amount due to varying circumstances.

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**Reviewed By: (Initial and Date)**

\_\_\_\_\_ Richard J. Oborn, Date \_\_\_/\_\_\_/\_\_\_

\_\_\_\_\_ W. Ray Walker, Date \_\_\_/\_\_\_/\_\_\_

\_\_\_\_\_ Mark B. Steinagel, Date \_\_\_/\_\_\_/\_\_\_

\_\_\_\_\_ Jennie Jonsson, Date \_\_\_/\_\_\_/\_\_\_



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

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

#### **R156-17b-101. Title.**

This rule is known as the "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) "ACPE" means the American Council on Pharmaceutical Education or Accreditation Council for Pharmacy Education.

(2) "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.

(3) "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.

(4) "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.

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

(6) "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.

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

(8) "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.

(9) "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.

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

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

(12) "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.

(13) "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."

(14) "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.

(15) "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.

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

(17) "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.

(18) "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.

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

~~(18)~~<sup>20</sup> "ExCPT", as used in this rule, means the Exam for the Certification of Pharmacy Technicians.

~~(19)~~<sup>21</sup> "FDA" means the United States Food and Drug Administration and any successor agency.

~~(20)~~<sup>22</sup> "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.

~~(24)~~<sup>23</sup> "Hospice facility pharmacy" means a pharmacy that supplies drugs to patients in a licensed healthcare facility for terminal patients.

~~(22)~~<sup>24</sup> "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.

~~(23)~~<sup>25</sup> "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".
- ([24]26) "Maintenance medications" means medications the patient takes on an ongoing basis.

([25]27) "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".

([26]28) "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.

([27]29) "MPJE" means the Multistate Jurisprudence Examination.

([28]30) "NABP" means the National Association of Boards of Pharmacy.

([29]31) "NAPLEX" means North American Pharmacy Licensing Examination.

([30]32) "Normal distribution channel" means a chain of custody for a prescription drug that goes directly, by drop shipment as defined in Subsection (14), 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.

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

([31]34) "Parenteral" means a method of drug delivery injected into body tissues but not via the gastrointestinal tract.

([32]35) "Pedigree" means a document or electronic file containing information that records each distribution of any given prescription drug.

([33]36) "PIC", as used in this rule, means the pharmacist-in-charge.

([34]37) "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.

([35]38) "PTCB" means the Pharmacy Technician Certification Board.

([36]39) "Qualified continuing education", as used in this rule, means continuing education that meets the standards set forth in Section R156-17b-309.

([37]40) "Refill" means to fill again.

([38]41) "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 responsible for dispensing the product to a patient.

(42) "Research facility" means a facility in which research takes place that has policies and procedures describing such research.

([39]42) "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.

([40]43) "Sterile products preparation facility" means any facility, or portion of the facility, that compounds sterile products using aseptic technique.

([41]44) "Supervisor" means a licensed pharmacist in good standing with the Division.

([42]45) "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".

([43]46) "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.

([44]47) "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 [expiration]beyond use date for the drug.

([45]48) "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.

([46]49) "USP-NF" means the United States Pharmacopeia-National Formulary (USP 36-NF 31), 2013 edition, which is official from May 1, 2013 through Supplement 2, dated December 1, 2012, which is hereby adopted and incorporated by reference.

([47]50) "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.

([48]51) "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)([e]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 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 Subsection 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-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 ~~[an approved program of education and training that meets the following standards]~~a training program that is accredited or conducted by the American Society of Health System Pharmacists, the National Pharmacy Technician Association, or a branch of the Armed Forces of the United States, and meets the following standards:

~~[(a) The didactic training program shall be approved by the Division in collaboration with the Board and shall address, at a minimum, the following topics:~~

~~(i) legal aspects of pharmacy practice including federal and state laws and rules governing practice;~~

~~(ii) hygiene and aseptic techniques;~~

~~(iii) terminology, abbreviations and symbols;~~

~~(iv) pharmaceutical calculations;~~

~~(v) identification of drugs by trade and generic names, and therapeutic classifications;~~  
~~(vi) filling of orders and prescriptions including packaging and labeling;~~  
~~(vii) ordering, restocking, and maintaining drug inventory;~~  
~~(viii) computer applications in the pharmacy; and~~  
~~(ix) non-prescription products including cough and cold, nutritional, analgesics, allergy, diabetic testing supplies, first aid, ophthalmic, family planning, foot, feminine hygiene, gastrointestinal preparations, and pharmacy care over the counter drugs, except those over the counter drugs that are prescribed by a practitioner.~~

~~(b) This training program's curriculum and a copy of the final examination shall be submitted to the Division for approval by the Board prior to starting any training session with a pharmacy technician in training. The final examination shall include questions covering each of the topics listed in Subsection (3)(a) above.~~

~~(c) Approval shall be granted by the Division in collaboration with the Board before a student may start a program of study. An individual who completes a non-approved program is not eligible for licensure.~~

~~(d) The training program shall include:~~

~~(i)(a) completion of at least 180 [but not more than 360] hours of directly supervised practical training in a licensed pharmacy as determined appropriate by [the supervisor] a licensed pharmacist in good standing; and~~

~~[(ii)(b) written protocols and guidelines for the teaching pharmacist outlining the utilization and supervision of pharmacy technicians in training that address:~~

~~[(A)i] the specific manner in which supervision will be completed; and~~

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

~~[(e)(i)(4) An individual shall complete [an approved] a pharmacy technician training program and successfully pass the required examinations as listed in Subsection R156-17b-303c[(b)(4) within two years from the date of the first day of the training program, unless otherwise approved by the Division in collaboration with the Board.~~

~~[(ii)a] An individual who [has completed an approved program, but did not seek licensure within the two-year time frame] 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:~~

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

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

~~(5) Pharmacy technician training programs that receive Division approval on or before April 30, 2014 are exempt from satisfying standards established in R156-17b-303a (3) until January 1, 2016. The Division shall accept and review applications for approval of pharmacy technician training programs submitted on or before March 31, 2014. The criteria used by the Division to determine whether a pharmacy technician program is approved shall be the criteria established in R156-17b-303a (2) of the rule effective immediately prior to this rule.~~

~~[(4)6] An applicant for licensure as a pharmacy technician 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) has engaged in the practice as a pharmacy technician for a minimum of 1,000 hours in that state within the past two years or equivalent experience as approved by the Division in collaboration with the Board;~~

(d) has passed the Utah Pharmacy Technician Law and Rule Examination.

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

(1) In accordance with Subsection 58-17b-303(1)(g), the standards for the pharmacy internship required for licensure as a pharmacist for graduates of all U.S. and foreign pharmacy schools, include the following:

(a) 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, 2001, which is hereby incorporated by reference.

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

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

(iii) 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.

(iv) 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.

(v) 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.

(b) 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.

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

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

(2) 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.

(3) 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.

**R156-17b-304. Temporary Licensure.**

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

(a) is a graduate of an ACPE accredited pharmacy school within two months immediately preceding application for licensure or enrolled in the second year of a pharmacy graduate residency program;

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

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

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

- (2) A temporary pharmacist license issued under Subsection (1) expires the earlier of:
  - (a) six months from the date of issuance;
  - (b) the date upon which the Division receives notice from the examination agency that the individual has failed either examination twice; or
  - (c) the date upon which the Division issues the individual full licensure.
- (3) An individual who has failed either examination twice shall meet with the Board to request an additional authorization to test. The Division, in collaboration with the Board, may require additional training as a condition for approval of an authorization to retest.
- (4) A pharmacist temporary license issued in accordance with this section cannot be renewed or extended.

**56-17b-305. Licensure - Pharmacist by Endorsement.**

(1) In accordance with Subsections 58-17b-303(3) and 58-1-301(3), an applicant for licensure as a pharmacist by endorsement shall apply through the "Licensure Transfer Program" administered by NABP.

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

- (a) lawfully practiced as a licensed pharmacist a minimum of 2,000 hours in the four years immediately preceding application in Utah;
- (b) obtained sufficient continuing education credits required to maintain a license to practice pharmacy in the state of practice; and
- (c) not had a pharmacist license suspended, revoked, canceled, surrendered, or otherwise restricted for any reason in any state for ten years prior to application in Utah, unless otherwise approved by the Division in collaboration with the Board.

**R156-17b-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-~~602~~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-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 of 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 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 or authorized supportive personnel to engage in any conduct in violation of this chapter, in violation of Subsection 58-17b-501(8):

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

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

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

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

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

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

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

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

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

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

subsequent offense(s): \$10,000

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

initial offense: \$100 - \$500

subsequent offense(s): \$1,000 - \$2,500

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

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

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

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

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

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

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

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

subsequent offense(s): \$10,000

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

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

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

(18) accepting back and redistributing any unused drugs, with the exception as provided in

Section 58-17b-503, in violation of Subsection 58-17b-502(5):

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

subsequent offense(s): \$10,000

(19) engaging in an act in violation of this chapter committed by a person for any form of compensation if the act is incidental to the person's professional activities, including the activities of a pharmacist, pharmacy intern, or pharmacy technician, 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 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 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: ~~[\$500]~~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, 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 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 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 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 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 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

#### **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) 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 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 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;

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

- [(18)19] dispensing medication that has been discontinued by the FDA;
- [(19)20] failing to keep or report accurate records of training hours;
- [(20)21] failing to provide PIC information to the Division within 30 days of a change in PIC;
- [(21)22] requiring a pharmacy, PIC, or any other pharmacist to operate the pharmacy or allow operation of the pharmacy with a ratio of supervising pharmacist to 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; ~~and~~
- [(22)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.]

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

In accordance with Subsection 58-17b-102([54]53), practice as a licensed pharmacy technician is defined as follows:

(1) The 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([55]53)(b)(2);
- (k) accepting new prescription drug orders left on voicemail for a pharmacist to review; ~~and~~
- (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 1 year of experience working as a pharmacy technician and at least 6 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 3 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) The pharmacy technician shall not receive new [~~verbal~~]prescriptions or medication orders as described in Subsection 58-17b-102 (53)(b)(iv), clarify prescriptions or medication orders nor perform drug utilization reviews. A new prescription, as used in Subsection 58-17b-102 (53)(b)(iv), does not include authorization of a refill of a legend drug.

(3) Pharmacy technicians, including no more than one pharmacy technician-in-training per shift, shall have [~~direct~~]general supervision by a pharmacist in accordance with Subsection R156-17b-603(2)(s).

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

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

#### **R156-17b-603. Operating Standards - Pharmacist-in-charge.**

(1) The PIC 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 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 email address shall be established by the PIC or responsible party for the pharmacy to be used for self-audits or pharmacy alerts initiated by the Division. The PIC 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 the initial application for licensure.

(3) The duties of the PIC shall include:

(a) assuring that pharmacists and pharmacy interns dispense 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) assuring that a pharmacist or pharmacy intern 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;

- (e) assuring that a reasonable effort is made to obtain, record and maintain patient medication records;
- (f) education and training of pharmacy technicians;
- (g) establishment of policies for procurement of prescription drugs and devices and other products dispensed from the pharmacy;
- (h) disposal and distribution of drugs from the pharmacy;
- (i) bulk compounding of drugs;
- (j) storage of all materials, including drugs, chemicals and biologicals;
- (k) 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) establishment and maintenance of effective controls against theft or diversion of prescription drugs and records for such drugs;
- (m) 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) 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;
- (o) assuring that any automated pharmacy 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;
- (p) 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) assuring that all relevant information is submitted to the Controlled Substance Database in the appropriate format and in a timely manner;
- (r) assuring that all personnel working in the pharmacy have the appropriate licensure;
- (s) assuring that no pharmacy or pharmacist operates the pharmacy or allows operation of the pharmacy with a ratio of pharmacist to 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) assuring that the PIC assigned to the pharmacy is recorded with the Division and that the Division is notified of a change in PIC within 30 days of the change; and
- (u) assuring with regard to the secure 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-605. Operating Standards - Inventory Requirements.**

- ~~[(1) General requirements for inventory of a pharmacy shall include the following:~~
- ~~(a) the PIC 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 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 of the opening of the business or the close of business on the inventory date;~~

~~(f) the person taking the inventory and the PIC 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 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 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 inventoried, the perpetual inventory shall be reconciled on the date of the inventory; and]~~

~~[(k)1] [a]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 [of expiration ]imprinted on the label.~~

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

(a) the PIC 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 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 of the opening of the business or the close of business on the inventory date;

(f) the person taking the inventory and the PIC 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 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 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 inventoried, the perpetual inventory shall be reconciled on the date of the inventory.

[(2)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 [none of the drugs specified in

~~paragraph (2)(a) of this section]~~ 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 (3) 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.

(3) 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.

(4) 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).

(5) Requirement for taking inventory when closing a pharmacy includes the PIC, 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.

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

### **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.

(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.

(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 at the pharmacy holding the prescription to a pharmacist or pharmacy intern 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 and receiving pharmacist or pharmacy intern 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 interns 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 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 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 to which such prescription is transferred; and

(E) the name of the pharmacist or pharmacy intern 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 may not refuse to transfer original prescription information to another pharmacist or pharmacy intern 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 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 from being able to contact the practitioner; or

(ii) the pharmacist 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 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 informs the practitioner of the emergency refill at the earliest reasonable time;
- (f) the pharmacist 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 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 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 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, in his 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 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(~~[28]~~[27]) through (~~[29]~~[28]), 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 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 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 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 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 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 general operating standards apply to all[for the operations for a] Class A and Class B [pharmacy include]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) 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) be equipped with a security system to permit detection of entry at all times when the facility is closed.

(2) The temperature of the pharmacy shall be maintained within a range compatible with the proper storage of drugs. The temperature of the refrigerator and freezer shall be maintained within a range compatible with the proper storage of drugs requiring refrigeration or freezing.

(3) Facilities engaged in 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 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 shall contain at a minimum:

(i) the formula;

(ii) the components;

(iii) the compounding directions;

(iv) a sample label;

(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) ~~expiration~~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;
  - (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) ~~[expiration]~~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 ~~[expiration]~~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 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 ~~[expiration]~~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 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) 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 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 of the initials or identification codes which identify each dispensing pharmacist by name. The initials or identification code shall be unique to ensure that each pharmacist 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 to sign DEA order forms (Form 222) shall be available to the Division whenever necessary.

(12) Pharmacists or other responsible individuals shall verify that ~~[the suppliers' invoices of legend drugs, including]~~ 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~~[and legend drugs]~~.

(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 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-615. Operating Standards - Class C Pharmacy - Pharmaceutical Wholesaler/Distributor and Pharmaceutical Manufacturer in Utah.**

In accordance with Subsections 58-17b-102([46]44) 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(14)(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. 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-[614]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 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 follow the USP-NF Chapter 795 Compounding of non-sterile preparations and Chapter 797 Compounding of sterile preparations.

**R156-17b-617e. Class E Pharmacy Operating Standards – Human Clinical Investigational Drug Research Facility**

(1) In accordance with Section 58-17b-302 and Subsection 58-17b-601(1), a human clinical investigational drug research facility licensed as a Class E Pharmacy shall, in addition to the requirements contained in Subsection R156-17b-617a, conduct operations in accordance with the operating standards set forth in 21 CFR Part 312, April 1, 2012 edition, which are hereby incorporated by reference.

(2) In accordance with Subsections 58-37-6(2)(b) and (3)(a)](i), persons licensed to conduct research with controlled substances in Schedules I-V within this state may possess, manufacture, produce, distribute, prescribe, dispense, administer, conduct research with, or perform laboratory analysis upon those substances to the extent authorized by their license.

(3) In accordance with Subsection 58-37-6(2), the following persons are not required to obtain a license and may lawfully possess controlled substances included in Schedules II-V:

(a) an agent or employee acting in the usual course of the person's business or employment, and

(b) an ultimate user, or any person who possesses any controlled substance pursuant to a lawful order of a practitioner.

(4) A separate license is required at each principal place of business or professional practice where the applicant manufactures, produces, distributes, dispenses, conducts research with, or performs laboratory analysis upon controlled substances.



4

## FW: Meeting to discuss new pharmacy in Utah for distribution of Baxter dialysis solutions to home patients

Stuman, William J <jay\_stuman@baxter.com>  
To: "roborn@utah.gov" <roborn@utah.gov>

Wed, Sep 25, 2013 at 3:39 PM

**From:** Stuman, William J  
**Sent:** Tuesday, September 10, 2013 9:09 AM  
**To:** 'roborn@utah.gov'  
**Cc:** Crates, William ([William.Crates@cardinalhealth.com](mailto:William.Crates@cardinalhealth.com)); Finerty, Patrick B  
**Subject:** Meeting to discuss new pharmacy in Utah for distribution of Baxter dialysis solutions to home patients

Mr. Osborne,

Thank you for returning my call yesterday. I enjoyed very much our conversation. As you requested I am sending you this email with more information about Baxter and what we are requesting in our meeting with you. In a recent press release the following is how Baxter describes itself:

"Baxter International Inc., through its subsidiaries, develops, manufactures and markets products that save and sustain the lives of people with hemophilia, immune disorders, infectious diseases, kidney disease, trauma, and other chronic and acute medical conditions. As a global, diversified healthcare company, Baxter applies a unique combination of expertise in medical devices, pharmaceuticals and biotechnology to create products that advance patient care worldwide"

As you can see one area that is part of Baxter's area of expertise is the treatment of kidney disease. As we discussed yesterday what we are requesting is setting up a new pharmacy in Utah for the distribution of dialysis solutions and products for home patients. This treatment of patients with kidney disease is a dialysis treatment called peritoneal dialysis.

What we are requesting is a pharmacy license for a closed door pharmacy located within the distribution center of Cardinal Healthcare. We have a national contract with Cardinal Healthcare for the distribution of Baxter products. Our request for a meeting with you is to discuss the unique pharmacy setup that we would have within this distribution center and what type of pharmacy license would be required to distribute the peritoneal dialysis solution to home

patients. There is no compounding at this pharmacy and the product would stay sealed from the time that we manufacture the product until it is delivered to the home patient. Security is of the utmost importance to us and the Cardinal Facility has one of the best state of the art security systems with very limited access to the building.

Your time frame for a meeting within the next two or three weeks works out very well for us. Just let me know what day and time and we work that time into our schedule.

Best Regards,

William J. Stuman

Manager, Pharmacy Operation

Supply Chain

Baxter Healthcare Corporation

Phone 205-365-2306

Fax 205-403-6528

Jay\_stuman@baxter.com

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For Translation:

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**Richard Oborn** <roborn@utah.gov>  
To: "Stuman, William J" <jay\_stuman@baxter.com>

Wed, Oct 16, 2013 at 9:20 AM

Jay,

Here is the agenda for the Utah Board of Pharmacy meeting next Tuesday. I've also attached a map showing different parking options. On the map, our building is the "DOPL" building. See you next week ...

[Quoted text hidden]

—  
Richard J. Oborn  
Bureau Manager  
Utah Department of Commerce  
Division of Occupational and Professional Licensing  
Phone: (801) 530-6767

**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) Based upon the pharmacist's or pharmacy intern's professional judgment; 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.

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

(3) A pharmacist shall not be required to counsel a patient or patient's agent when the patient or patient's agent refuses such consultation.

(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) Counseling shall be:

(a) provided with each new prescription drug order, once yearly on maintenance medications, and if the pharmacist deems appropriate with prescription drug refills;

(b) provided for any prescription drug order dispensed by the pharmacy on the request of the patient or patient's agent; and

(c) communicated verbally in person unless the patient or the patient's agent is not at the pharmacy or a specific communication barrier prohibits such verbal communication.

(6) Only a pharmacist or pharmacy intern may verbally provide drug information to a patient or patient's agent and answer questions concerning prescription drugs.

(7) In addition to the requirements of Subsections (1) through (6) of this section, if a prescription drug order is delivered to the patient at the pharmacy, a filled prescription may not be delivered to a patient unless a pharmacist is in the

pharmacy. However, an agent of the pharmacist may deliver a prescription drug order to the patient or the patient's agent if the pharmacist is absent for ten minutes or less and provided a record of the delivery is maintained and contains the following information:

- (a) date of the delivery;
- (b) unique identification number of the prescription drug order;
- (c) patient's name;
- (d) patient's phone number or the phone number of the person picking up the prescription; and

- (e) signature of the person picking up the prescription.

(8) 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.

**R156-17b-617c. Class E Pharmacy Operating Standards – Animal [Euthanasia]Control**

(1) In accordance with Section 58-17b-302 and Subsection 58-17b-601(1), an animal [euthanasia]control 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 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 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 [euthanasia]control 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 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 upon 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.