



State of Utah  
Department of Commerce

Division of Occupational and Professional Licensing

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November 6, 2014

**SUBJECT: Request for Input Regarding Pharmacy Practice Rule Amendments Impacting Your Profession**

Dear Board Member:

The purpose of this letter is to request your input regarding the attached proposed amendments to the Pharmacy Practice Act Rule (Utah Admin. Code R156-17b). Your input is important because these particular rule amendments will impact some licensees within your profession.

The rule amendments are required under Senate Bill 55 which became effective on July 1, 2014. SB 55 created two license categories: dispensing medical practitioner (DMP) and dispensing medical practitioner (DMP) clinic pharmacy. The paragraphs below outline key elements of the statute but are not intended to summarize all provisions that may impact your profession.

- Licensed physicians, osteopathic physicians, physician assistants, nurse practitioners, and optometrists are eligible to apply for a DMP license.
- A DMP's ability to dispense is limited to a cosmetic drug, an injectable weight loss drug, a cancer drug treatment regimen, or a prepackaged drug at an employee sponsored clinic.
- A DMP clinic pharmacy cannot dispense a controlled substance unless it is a cancer drug treatment regimen clinic which may dispense only schedule IV and V controlled substances.
- A DMP cannot dispense at any clinic other than a DMP clinic pharmacy licensed by DOPL.
- A DMP clinic pharmacy is classified as a Class B Closed Door Pharmacy but is not required to employ a pharmacist.
- A DMP clinic pharmacy must identify a "responsible DMP" who is responsible for the pharmacy activities.
- A DMP may delegate the dispensing of a drug to a "DMP designee" if the designee is employed by the DMP or the outpatient clinic setting in which the DMP works.
- The DMP designee acts under the direction of a DMP practitioner. The DMP practitioner must be immediately available onsite to the DMP designee for any necessary consultation.

- A DMP designee may enter medication profile information into a DMP clinic pharmacy's computer system and engage in compounding because these tasks are sometimes part of the drug dispensing process. The statute does not allow a DMP designee to engage in patient counseling for drugs dispensed at the DMP clinic pharmacy.

After reviewing the statute, DOPL created a task force of key stakeholders to assist with drafting rules to support SB 55. The task force was comprised of representatives of the Utah Medical Association, Utah Pharmacists Association, Utah Food Industry Association, Utah Nurses Association, and other interested parties. After several meetings and multiple revisions, the attached draft of proposed rules emerged. Key elements of the attached draft are outlined in the paragraphs below.

- **DMP Designees.** An individual that may dispense drugs under the on-site supervision of a DMP is defined as a "DMP designee" in Section 102. A DMP designee must: (1) hold an active health care professional license or be a medical assistant; (2) be employed by the DMP or the outpatient clinic setting in which the DMP works; and (3) have documentation demonstrating successful completion of a formal or on-the-job dispensing training program that meets standards established in Section 622.
- **Dispensing Training Program.** DMP designees are required to complete a formal or on-the-job dispensing training program that meets standards established in Section 622. Programs do not require DOPL approval; however, programs must cover topics outlined in Section 622 to the extent that the topics are relevant and current to a particular DMP practice. For example, if a DMP clinic pharmacy does not engage in sterile or non-sterile compounding, their training program is not required to cover that topic. There is not a minimum number of hours that a DMP designee must spend in a training program. A DMP clinic pharmacy may create its own on-the-job training program.
- **Other Key Elements.** The proposed rules make several other amendments that impact DMP clinic pharmacies. These include setting various operating standards for facility security systems, facility pharmacy temperature, and patient counseling for drugs dispensed.

Please review the attached draft and contact me by **November 19, 2014** with any comments or questions.

Sincerely,

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

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

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

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

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

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

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

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

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

### **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: ...

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

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

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

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

"Unprofessional conduct" includes:

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

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

(3) failing to comply with the continuing education requirements;

(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/DMP standards as established in Section R156-17b-603;
- (17) failing to adhere to institutional policies and procedures related to technician checking of medications when technician checking is utilized;
- (18) failing to take appropriate steps to avoid or resolve identified drug therapy management problems as referenced in Subsection R156-17b-611(3);
- (19) dispensing medication that has been discontinued by the FDA;
- (20) failing to keep or report accurate records of training hours;
- (21) failing to provide PIC or responsible DMP information to the Division within 30 days of a change in PIC or responsible DMP;
- (22) requiring a pharmacy, [~~PIC, or any other~~] pharmacist, or DMP to operate the pharmacy or allow operation of the pharmacy with a ratio of supervising pharmacist or DMP to other pharmacy [~~technician/pharmacy intern/support~~] personnel which, under the circumstances of the particular practice setting, results in, or reasonably would be expected to result in, an unreasonable risk of harm to public health, safety, and welfare;
- (23) failing to update the Division within seven calendar days of any change in the email address designated for use in self-audits or pharmacy alerts; [~~and~~]
- (24) effective November 30, 2014, failing to comply with prescription container label standards established in USP-NF Chapter 17[-]; and
- (25) if licensed as a DMP or DMP clinic pharmacy, delegating the dispensing of a drug to a DMP designee who has not completed a formal or on-the-job dispensing training program that meets standards established in Section R156-17b-622.

**R156-17b-603. Operating Standards - Pharmacist-in-charge and responsible dispensing medical practitioner.**

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

charge of the pharmacy.

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

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

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

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

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

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

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

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

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

~~[(d)c]~~ assuring that a pharmacist, ~~[or]~~ pharmacy intern, or DMP communicate[s] 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]~~pharmacy;

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

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

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

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

~~[(i)h]~~ bulk compounding of drugs;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) the anticipated date of closing;

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

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

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

(a) the date of closing; and

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

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

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

(b) transfer, sell or give away prescription drugs to a person who is legally

entitled to possess drugs, such as a hospital or another pharmacy.

(4) If the pharmacy dispenses prescription drug orders:

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

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

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

- (a) the actual date of closing;
- (b) the license issued to the pharmacy;
- (c) a statement attesting:
  - (i) that an inventory as specified in Subsection R156-17b-605(5) has been conducted; and
  - (ii) the manner in which the legend drugs and controlled substances possessed by the pharmacy were transferred or disposed;
- (d) if the pharmacy dispenses prescription drug orders, the name and address of the pharmacy to which the prescription drug orders, including refill information and patient medication records, were transferred.

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

- (a) DEA registration certificate;
- (b) all unused DEA order forms (Form 222) with the word "VOID" written on the face of each order form; and
- (c) copy #2 of any DEA order forms (Form 222) used to transfer Schedule II controlled substances from the closed pharmacy.

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

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

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

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

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

imprinted on the label.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(4) Requirement for annual controlled substances inventory shall be within 12

months following the inventory date of each year and may be taken within four days of the specified inventory date and shall include all stocks including out-of-date drugs and drugs in automated pharmacy systems.

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

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

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

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

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

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

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

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

(a) stock ordering and restocking;

(b) cashiering;

(c) billing;

(d) filing;

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

(f) housekeeping; and

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

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

(3) In accordance with Subsection 58-17b-102(~~[66]~~69)(b), ~~the supervision of supportive personnel is defined as follows:~~

~~(a) all supportive personnel shall be under the supervision of a licensed pharmacist or DMP; and]~~

(b) the licensed pharmacist or DMP shall be present in the area where the person being supervised is performing services and shall be immediately available to assist the person being supervised in the services being performed except for the delivery of prefilled prescriptions as provided in Subsection (1)(g) above.

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

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

A pharmacy that employs the United States Postal Service or other common carrier to deliver a filled prescription directly to a patient shall, under the direction of the ~~[pharmacist in charge]~~ PIC, responsible DMP, or other responsible employee:

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

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

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

(4) provide for an electronic, telephonic, or written communication mechanism for a ~~pharmacy~~ pharmacist, or a ~~pharmacy intern working under the direct supervision of a pharmacist,~~ to offer counseling to the patient as defined in Section 58-17b-613 and there shall be documentation of such counseling; and

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

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

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

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

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

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

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

(i) name of prescription drug;

(ii) strength of prescription drug;

(iii) quantity dispensed;

(iv) date of filling or refilling;

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

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

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

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

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

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

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

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

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

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

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

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

(b) if prescriptions are routinely delivered outside the area covered by the pharmacy's local telephone service, the pharmacist or DMP 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 or dispensing medical practitioner is available during normal business hours to answer

these questions."; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

date of issuance;

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

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

(D) the name and address of the pharmacy and the name of the pharmacist, ~~or~~ pharmacy intern, or DMP to which such prescription is transferred; and

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

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

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

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

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

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

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

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

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

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

(b) either:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(iv) the date and time of the transfer.

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

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

**LIGHTING**

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

**SEPARATE SINK**

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

**ORDERLY STORAGE**

(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;

**EQUIPPED TO PERMIT ETHICAL PRACTICE**

(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;

**ADEQUATE STOCK**

(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

**SECURITY SYSTEM**

(f) if dispensing controlled substances, be equipped with a security system to:  
(i) permit detection of entry at all times when the facility is closed; and  
(ii) provide notice of unauthorized entry to an individual[ ~~who is able to respond quickly and reasonably assess the entry and resolve the matter~~]; and

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

## PHARMACY TEMPERATURE

(2) The temperature of the pharmacy shall be maintained within a range compatible with the proper storage of drugs. If a refrigerator or freezer is necessary to properly store drugs at the pharmacy, [F]the pharmacy shall keep a daily written or electronic log of the temperature of the refrigerator [and] or freezer on days of operation for not less than three years [~~shall be maintained within a range compatible with the proper storage of drugs requiring refrigeration or freezing~~].

## COMPOUNDING

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

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

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

(c) bulk active ingredients shall:

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

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

(d) a master worksheet sheet shall be [~~developed and~~] approved by a pharmacist or DMP for each batch of sterile or non-sterile pharmaceuticals to be prepared. Once approved, a duplicate of the master worksheet sheet shall be used as the preparation worksheet sheet from which each batch is prepared and on which all documentation for that batch occurs. The master worksheet sheet 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) beyond use date of batch prepared products;
  - (vii) date of preparation;
  - (viii) name, initials or electronic signature of the person or persons involved in the preparation;
  - (ix) names, initials or electronic signature of the responsible pharmacist or DMP;
  - (x) end-product evaluation and testing specifications, if applicable; and
  - (xi) comparison of actual yield to anticipated yield, when appropriate;
- (f) the label of each batch prepared of sterile or non-sterile pharmaceuticals shall bear at a minimum:
- (i) the unique lot number assigned to the batch;
  - (ii) all solution and ingredient names, amounts, strengths and concentrations, when applicable;
  - (iii) quantity;
  - (iv) beyond use date and time, when applicable;
  - (v) appropriate ancillary instructions, such as storage instructions or cautionary statements, including cytotoxic warning labels where appropriate; and
  - (vi) device-specific instructions, where appropriate;
  - (g) the beyond use date assigned shall be based on currently available drug stability information and sterility considerations or appropriate in-house or contract service stability testing;
    - (i) sources of drug stability information shall include the following:
      - (A) references can be found in Trissel's "Handbook on Injectable Drugs", 17th Edition, October 31, 2012;
      - (B) manufacturer recommendations; and
      - (C) reliable, published research;
    - (ii) when interpreting published drug stability information, the pharmacist or DMP shall consider all aspects of the final sterile product being prepared such as drug reservoir, drug concentration and storage conditions; and
    - (iii) methods for establishing beyond use dates shall be documented; and
    - (h) there shall be a documented, ongoing quality control program that monitors and evaluates personnel performance, equipment and facilities that follows the USP-NF Chapters 795 and 797 standards.

#### **PUBLICATIONS READILY AVAILABLE**

- (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.

### **POSTING OF LICENSES**

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

### **DESIGNATED COUNSELING AREA**

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

### **CLOSED WHEN PHARMACIST NOT IMMEDIATELY AVAILABLE**

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

### **AUTHORIZED ACCESS**

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

### **LOG OF CODES OF EACH DISPENSING PHARMACIST**

(9) The facility or parent company shall maintain a [permanent log] record for not

less than 5 years of the initials or identification codes which identify each dispensing pharmacist or DMP by name. The initials or identification code shall be unique to ensure that each pharmacist or DMP can be identified; therefore identical initials or identification codes shall not be used.

### **CONTROLLED SUBSTANCE STANDARDS**

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

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

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

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

### **INVENTORY RECORDS**

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

### **HARD COPY OF SURRENDER OR DESTRUCTION RECORDS**

(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.

### **DROP/FALSE CEILING**

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

### **R156-17b-622. Standards - Dispensing Training Program**

(1) In accordance with Subsection R156-17b-102 (16), a formal or on-the-job dispensing training program completed by a DMP designee is one which covers the following topics to the extent that they are relevant and current to the DMP practice where the DMP designee is employed:

(a) role of the DMP designee;

(b) laws affecting prescription drug dispensing;

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

(d) pharmaceutical terminology, abbreviations and symbols;

(e) pharmaceutical calculations;

(f) drug packaging and labeling;

(g) computer applications in the pharmacy;

(h) sterile and non-sterile compounding;

(i) medication errors and safety;

(j) prescription and order entry and fill process;

(k) pharmacy inventory management; and

(l) pharmacy billing and reimbursement.

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

(a) name of individual trained;

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

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

(d) training completion date.