

Pharmacy Board Report
May 2014

#1

	2013	2014	May-14
Administrative Filings	37	16	11
Criminal Filing/Felony	3	0	0
Letter of Concern	60	61	5
PR/Outreach	3	2	2
Cases Received	710	218	28
Case Assigned	676	212	28
Closed Cases	731	250	35
Citations Issued	103	7	2
Pharmacy Inspections	225	102	14
Pharmacy Alerts	191	79	23
Dr. Shopper/Law Enforcement Letters	209	144	67

NOTES: Pharmacy Group

May-14

New Positions

The Division received numerous applications for the Pharmacy Investigator and Pharmacy Inspector positions. Interviews were conducted on June 18-19, 2014.

Administrative Action

The Division took action against a Pharmacist-In-Charge, Gregg Luke, for numerous pharmacy violations. The licensee entered into a Stipulation and Order with a \$2,500 fine.

Administrative Action

The Division took action against a Pharmacist-In-Charge, Richard Ballam, for numerous pharmacy violations. The licensee entered into a Stipulation and Order with a \$2,500 fine.

Administrative Action

The Division took action against Bear Lake Community Health Center, Inc. for dispensing controlled substances in the State of Utah without being licensed to do so. Bear Lake Community Health Center, Inc. entered into a Stipulation and Order, Cease and Desist, with a \$5,000 fine.

Administrative Action

The Division took action against Bear Lake Community Health Center Pharmacy for pharmacy violations, and dispensing violations. The licensee entered into a Stipulation and Order with a \$5,000 fine.

Pharmacy Board Report
May 2014

Administrative Action

The Division took action against Bear Lake Community Health Center, Inc. dba Cache Valley Community Health Center for practicing as a pharmacy and dispensing controlled substance in the State of Utah without a license. Bear Lake Community Health Center, Inc. dba Cache Valley Community Health Center entered into a Stipulation and Order, Cease and Desist, with a \$5,000 fine.

Administrative Action

The Division took action against Cache Valley Community Health Center Pharmacy for dispensing and pharmacy violations. The licensee entered into a Stipulation and Order with a \$5,000 fine.

Administrative Action

The Division took action against IHC Health Center in Layton for numerous pharmacy violations. The licensee entered into a Stipulation and Order, with a \$5,000 fine.

Citation

Brigham Community Pharmacy was issued a Citation during a random inspection for pharmacy violations.



Compounded Mouthwash Guidelines

Updated June 23, 2014

This document is intended to be an informal guide to pharmacies that dispense compounded mouthwashes used to treat mouth sores. Examples of compounded mouthwashes include those containing Antacid, Diphenhydramine, and Viscous Lidocaine (1:1:1) liquid ingredients. These preparations are classified as "moderate compounds" by the Utah Division of Occupational and Professional Licensing (DOPL) and the Utah Board of Pharmacy.

Under Utah Admin. Code R156-17b-614a (3), a pharmacy engaged in moderate compounding must comply with certain documentation, equipment, and training standards established in USP-NF 795. Some key provisions of USP-NF 795 are summarized in the paragraphs below; however, a pharmacy is responsible to review and comply with USP-NF 795 in its entirety. Legal advice should be obtained if necessary. USP-NF 795 governs in the case of any discrepancy between this guide and USP-NF 795. USP-NF 795 can be viewed online at www.usp.org.

- **Standard Operating Procedures.** The pharmacy must have a Standard Operating Procedure (SOP) on the premises to show how the compound will be made. This must include a description of the equipment and procedure use to make the compound.
- **Equipment.** In order to accurately measure ingredients of a Magic Mouthwash, graduated cylinders of appropriate size must be available in the pharmacy.
- **Good Compounding Practice.** The work area must be clean and orderly, including any measuring devices. Good personal hygiene must be followed and water must be distilled or purified.
- **Master Formulation Record.** Each compound must have a Master Formulation Record (MFR). Compounds must contain the following information:
 - name, strength, dosage form of the preparation;
 - calculations required to determined and verify quantities of components and doses of active pharmaceutical ingredients;
 - description of ingredients and their quantities;
 - compatibility and stability information, including references if appropriate;
 - equipment required to prepare preparation;
 - detailed mixing instructions;
 - sample labeling information including: generic name and quantity or concentration of each active ingredient, assigned Beyond Use Date

- (BUD), storage conditions, and prescription or control number;
- packaging and storage requirements;
- description of final preparation; and
- quality control measures and expected results.

The MFR is a permanent record kept at the pharmacy. It is the reference used to make this version of the compound each time. If the compound is altered from the MFR, a new MFR must be created for the variation.

- **Compounding Record (CR).** This is the record for each individual compound made. The CR must contain the following information:
 - name, strength and dosage form of the preparation;
 - MFR reference for the preparation;
 - names and quantities of all components;
 - source, lot numbers and expiration dates of components;
 - total quantity compounded;
 - name of person(s) who prepared the preparation, who performed the quality control procedures, and who approved the preparation;
 - date of preparation;
 - assigned control or RX number;
 - assigned BUD;
 - duplicate label as described in the MFR;
 - description of final preparation;
 - results of quality control procedures; and
 - documentation of any quality control issues and any adverse reactions or preparation problems reported by patient or caregiver.

The CR may be kept either in a designated location, such as a binder, or attached to the hard copy of the prescription. It must be kept for as long as a hard copy is retained. Pharmacies may create a blank CR to fill in each time a Magic Mouthwash is made.

- **Naming the Compound.** Although the term Magic Mouthwash is commonly used, the prescription must be named with its active ingredients. For example, Lidocaine:diphenhydramine:antacid 1:1:1 mouthwash is an acceptable compound name. Abbreviations are acceptable if the abbreviation lends itself to only one drug.
- **Labeling.** The following statement must appear on all compounded preparations: this is a compounded preparation. Any appropriate auxiliary labels must be attached. For example: shake well, refrigerate.

- **Beyond Use Date (BUD).** The BUD is 30 days at room temperature for oral mucosal preparations, and 14 days refrigerated for oral preparations (swallowed). The BUD must appear on the prescription label.
- **Storage and Handling of Rx.** Any appropriate storage and handling instructions must be included with the prescription.
- **Training Documentation.** Documentation of training is required for all personnel involved in the making of the compound. Training must include familiarity with the SOP, calibration of scale (if appropriate), how the compound is made, and how the compound is documented. Training must be completed annually.

If a pharmacy making compounded mouthwash complies with standards established in Utah Admin. Code R156-17b-614a (3) and USP-NF 795, it would be in compliance with compounding standards established in Utah law.

^ Epaned Solution (enalapril 1 mg/mL):

1. 150 mL of Ora-Sweet SF
 2. 150 mg powder blend of:
 - a. Mannitol
 - b. Colloidal silicon dioxide
 - c. Enalapril
 3. Final volume: 150 mL (1 mg/mL)
 4. BUD: 60 days room temperature
-

> Vasotec Suspension (enalapril 1 mg/mL):

1. 50 mL of Bicitra (Citric acid/Sodium citrate buffer)
2. 150 mL of Ora-Sweet SF
3. 20 mg enalapril tablets x 10
4. Final volume: 200 mL (1 mg/mL)
5. BUD: 30 days refrigerated

^ Local Hospital Enalapril Suspension (1 mg/mL):

1. 60 mL of Ora-Sweet
2. 60 mL of Ora-Plus
3. Enalapril 5 mg tablets x 24
4. Final volume: 120 mL (1 mg/mL)
5. BUD: 90 days room temperature/refrigerated

, AJHP Enalapril Suspension (1 mg/mL):

1. 100 mL of Ora-Sweet
2. 100 mL of Ora-Plus
3. Enalapril 10 mg tablets x 20
4. Final volume: 200 mL (1 mg/mL)
5. BUD: 91 days room temperature/refrigerated



(no subject)

4 messages

David Zeiger <David.Zeiger@priorityco.com>

Wed, Jun 4, 2014 at 3:31 PM

To: "roborn@utah.gov" <roborn@utah.gov>

Hello Mr. Oborn,

I am writing this e-mail so as to facilitate the issuing of a wholesale license at the same address as a licensed pharmacy employing a self contained area that is under the control of the PIC of the retail pharmacy. As we discussed the purpose of issuing a wholesale license to our sourcing partner pharmacies is solely for the pass through transfer of non DEA dangerous drugs to comply with Federal law, which I have attached for your convenience, that removes the 5% rule but does require that the retail pharmacy obtain a wholesale license in their domiciled State. To that end the sole purpose of the license is to legally transfer product from the retail licensee to the wholesale licensee both being under the same control and ownership, effectively intercompany transfers. All orders are for emergency needs/small quantities for acute care hospitals. Many of our partner pharmacies have space limitations so we are suggesting a lockable wire cage that sits in the pharmacy drug storage area that is not accessible to the public. The key would be held by the PIC. Forgive me if this seems unusual but then again our business model is rather unique. The day product arrives it is either picked up in person by our DR or in the alternative that afternoon by FedEx to be delivered to our SLC licensed facility. In reality it is a virtual inventory compared to a retail or wholesaler's traditional inventory levels.

Hopefully this will meet the controls necessary to alleviate the possibility of diversion and identify a separate carved out space. If DOPL and/or the BOP would like me to stipulate or go on the record I am readily available to do so.

Best regards,

Dave

Priority Pharmaceuticals, Inc.

Dave Zeiger, Pharm.B/CEO

4040 Sorrento Valley Blvd, Su D

San Diego, Calif. 92121-1415

1-858 -761-1886 M

58-17b-302. License classifications of pharmacy facilities.

- (1) A license is required to act as a pharmacy, except as specifically exempted from licensure under Section 58-1-307 or 58-17-309.6.
- (2) The division shall issue a pharmacy license to a facility that qualifies under this chapter in the classification of a:
 - (a) class A pharmacy;
 - (b) class B pharmacy;
 - (c) class C pharmacy;
 - (d) class D pharmacy; or
 - (e) class E pharmacy.
- (3) **Each place of business shall require a separate license. If multiple pharmacies exist at the same address, a separate license shall be required for each pharmacy.**
- (4) The division may further define or supplement the classifications of pharmacies. The division may impose restrictions upon classifications to protect the public health, safety, and welfare.
- (5) Each pharmacy shall have a pharmacist-in-charge, except as otherwise provided by rule.
- (6) Whenever an applicable statute or rule requires or prohibits action by a pharmacy, the pharmacist-in-charge and the owner of the pharmacy shall be responsible for all activities of the pharmacy, regardless of the form of the business organization.

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

(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.

58-37f-203. Submission, collection, and maintenance of data.

- (1) The pharmacist in charge of the drug outlet where a controlled substance dispensed shall submit the data described in this section to the division:
 - (a) in accordance with the requirements of this section;
 - (b) in accordance with the procedures established by the division; and
 - (c) in the format established by the division.
- (2) The pharmacist described in Subsection (1) shall, for each controlled substance dispensed by a pharmacist under the pharmacist's supervision other than those dispensed for an inpatient at a health care facility, submit to the division the following information:
 - (a) the name of the prescribing practitioner;
 - (b) the date of the prescription;
 - (c) the date the prescription was filled;
 - (d) the name of the individual for whom the prescription was written;
 - (e) **positive identification of the individual receiving the prescription, including the type of identification and any identifying numbers on the identification;**
 - (f) the name of the controlled substance;
 - (g) the quantity of controlled substance prescribed;
 - (h) the strength of controlled substance;
 - (i) the quantity of controlled substance dispensed;
 - (j) the dosage quantity and frequency as prescribed;
 - (k) the name of the drug outlet dispensing the controlled substance;
 - (l) the name of the pharmacist dispensing the controlled substance; and
 - (m) other relevant information as required by division rule.

58-17b-102. Definitions.

In addition to the definitions in Section 58-1-102, as used in this chapter:

- (54) "Practice of pharmacy" includes the following:
- (a) providing pharmaceutical care;
 - (b) **collaborative pharmacy practice in accordance with a collaborative pharmacy practice agreement;**
 - (c) compounding, packaging, labeling, dispensing, **administering**, and the coincident distribution of prescription drugs or devices, **provided that the administration of a prescription drug or device is:**
 - (i) **pursuant to a lawful order of a practitioner when one is required by law; and**
 - (ii) **in accordance with written guidelines or protocols:**
 - (A) **established by the licensed facility in which the prescription drug or device is to be administered on an inpatient basis; or**
 - (B) **approved by the division, in collaboration with the board and the Physician's Licensing Board, created in Section 58-67-201, if the prescription drug or device is to be administered on an outpatient basis solely by a licensed pharmacist;**
 - (d) participating in drug utilization review;
 - (e) ensuring proper and safe storage of drugs and devices;
 - (f) maintaining records of drugs and devices in accordance with state and federal law and the standards and ethics of the profession;
 - (g) providing information on drugs or devices, which may include advice relating to therapeutic values, potential hazards, and uses;
 - (h) providing drug product equivalents;
 - (i) supervising pharmacist's supportive personnel, pharmacy interns, and pharmacy technicians;
 - (j) providing patient counseling, including adverse and therapeutic effects of drugs;
 - (k) providing emergency refills as defined by rule;
 - (l) telepharmacy; and
 - (m) formulary management intervention.

- (1) "Administering" means:
 - (a) the direct application of a prescription drug or device, whether by injection, inhalation, ingestion, or by any other means, to the body of a human patient or research subject by another person; or
 - (b) the placement by a veterinarian with the owner or caretaker of an animal or group of animals of a prescription drug for the purpose of injection, inhalation, ingestion, or any other means directed to the body of the animal by the owner or caretaker in accordance with written or verbal directions of the veterinarian.

- (16) "Collaborative pharmacy practice" means a practice of pharmacy whereby one or more pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or more practitioners under protocol whereby the pharmacist may perform certain pharmaceutical care functions authorized by the practitioner or practitioners under certain specified conditions or limitations.

- (17) "Collaborative pharmacy practice agreement" means a written and signed agreement between one or more pharmacists and one or more practitioners that provides for collaborative pharmacy practice for the purpose of drug therapy management of patients and prevention of disease of human subjects.

R156-17b-621. Operating Standards - Pharmacist Administration - Training.

- (1) In accordance with Subsection 58-17b-502(9), appropriate training for the administration of a prescription drug includes:
 - (a) current Basic Life Support (BLS) certification; and
 - (b) successful completion of a training program which includes at a minimum:
 - (i) didactic and practical training for administering injectable drugs;
 - (ii) the current Advisory Committee on Immunization Practices (ACIP) of the United States Center for Disease Control and Prevention guidelines for the administration of immunizations; and
 - (iii) the management of an anaphylactic reaction.
- (2) Sources for the appropriate training include:
 - (a) ACPE approved programs; and
 - (b) curriculum-based programs from an ACPE accredited college of pharmacy, state or local health department programs and other Board recognized providers.
- (3) Training is to be supplemented by documentation of two hours of continuing education related to the area of practice in each preceding renewal period.
- (4) The "Vaccine Administration Protocol: Standing Order to Administer Immunizations and Emergency Medications", adopted March 27, 2012, by the Division in collaboration with the Utah State Board of Pharmacy, as posted on the Division website, is the guideline or standard for pharmacist administration of vaccines and emergency medications.

58-17b-502. Unprofessional conduct.

"Unprofessional conduct" includes:

- (9) administering:
 - (a) without appropriate training as defined by rule;
 - (b) without a physician's order, when one is required by law; and
 - (c) in conflict with a practitioner's written guidelines or written protocol for administering;



State of Utah Department of Commerce

Division of Occupational and Professional Licensing

GARY R. HERBERT
Governor

FRANCINE A. GIANI
Executive Director

MARK B. STEINAGEL
Division Director

VACCINE ADMINISTRATION PROTOCOL Standing Order to Administer Immunizations and Emergency Medications

Approved March 27, 2012

(54) The following pharmacist(s), according to and in compliance with Utah Code 58-17b-102 (16-17) and (56) (b-c) and Utah Code 58-17b-502 (9) of the Utah State Pharmacy Practice Act, may administer medications for a fee. Each below-mentioned pharmacist has completed training as prescribed in Utah Administrative Code R156-17b-621 of the Pharmacy Practice Act Rules.

To protect people from preventable infectious diseases, each pharmacist may administer the following immunizations to eligible patients for all appropriate ages, according to indications and contraindications recommended in current guidelines from the Advisory Committee on Immunization Practices (ACIP) of the U.S. Centers for Disease Control and Prevention (CDC) and local/state health departments.

Influenza	Hepatitis B	Tetanus-Diphtheria Toxoids
Hepatitis A	Meningococcal	Pneumococcal
Varicella	Herpes Zoster	Haemophilus Influenza type b
Measles-Mumps-Rubella	Human Papilloma Virus	
Inactivated Polio	Tetanus-Diphtheria Acellular Pertussis	

Striking through the name of any of the above vaccines will indicate deletion from this protocol. Additions must be submitted in writing to the Utah Division of Occupational and Professional Licensing (DOPL) for approval.

No pharmacist may delegate the administration of immunizations to another person, except for a licensed intern who has completed training as prescribed in Utah Administrative Code R156-17b-621 of the Pharmacy Practice Act Rules and who is practicing under the direct supervision of a pharmacist who has completed training as prescribed in Utah Administrative Code R156-17b-621 of the Pharmacy Practice Act Rules.

The pharmacy shall post in a prominent place an emergency plan to be implemented in case of an adverse event. Such plan shall include: the phone number of the local EMS, the phone number of the undersigned licensed practitioner, and the roles of the pharmacist and other participants.

In the course of treating adverse events following immunization, the pharmacist is authorized to administer:

- epinephrine (at a dose of approximately 0.01mg/kg body weight; maximum of 0.5mg per dose) and
- diphenhydramine (at a dose of approximately 1.0mg/kg; maximum dose of 50-100mg per dose) by appropriate routes pending availability of emergency medical services.

The pharmacist may provide cardiopulmonary resuscitation as needed.

For adverse events, the pharmacist shall complete and submit the Vaccine Adverse Event Reporting System (VAERS) form to the CDC, the undersigned licensed practitioner, and the patient's primary care practitioner, if known.

In the course of immunizing, the pharmacist shall maintain perpetual records of all immunizations administered, including: patient name; primary care practitioner (if known); vaccination date; name, address, title of administering pharmacist; name of vaccine; manufacturer; and lot number. Before immunization, all vaccine candidates will be questioned regarding previous adverse events after immunization, food or drug allergies, current health conditions, recent receipt of blood or antibody products, immunosuppression, pregnancy, and underlying diseases.

All vaccine candidates will be informed of the specific benefits and risks of the vaccine(s) offered. Each pharmacist participating in a vaccine immunization collaborative practice agreement will obtain training related to the study of immunizations and associated patient care as described in R156-17b-621.

The pharmacist shall report administered immunizations to the Utah State Immunization Information System (USIIS) electronic registry. Updates to the USIIS registry will be completed within one week of any vaccine administered. Register for UCIIS: http://www.usiis.org/howtoparticipate_provider.shtml.

As the authorizing licensed practitioner, I will periodically review (not less than annually) the activities of the pharmacist(s) administering vaccines under this protocol and deem authorization valid one year from the date indicated below, unless otherwise revoked or extended in writing.

Pharmacist: License Number: _____ **Pharmacist: License Number:** _____

Pharmacist: License Number: _____ **Pharmacist: License Number:** _____

Pharmacist: License Number: _____ **Pharmacist: License Number:** _____

Licensed Practitioner Name: _____

Licensed Practitioner Signature: _____ **Date:** _____

Address: _____

City: _____ **State:** _____ **Zip:** _____

Practitioner License Number: _____ **State** _____

Prescription Order to Administer Immunizations and Emergency Medications

Pharmacist(s), according to and in compliance with Utah Code 58-17b-102 ⁽⁵⁴⁾~~(50)~~(c) and Utah Code 58-17b-502 (9) of the Utah State Pharmacy Practice Act who have completed training as prescribed in Utah Administrative Code R156-17b-621 of the Pharmacy Practice Act Rules, may administer medications for a fee.

To protect people from preventable infectious diseases, pharmacist(s) may administer, pursuant to a prescription from a licensed prescriber, any immunization(s) that are not listed in the current VACCINE PROTOCOL: Standing Order to Administer Immunizations and Emergency Medications. This protocol is approved by the Division, in collaboration with the Pharmacy Board and the Physician's Licensing Board, created in Section 58-67-201 according to indications and contraindications recommended in current guidelines from the Advisory Committee on Immunization Practices (ACIP) of the U.S. Centers for Disease Control and Prevention (CDC) and local/state health departments

No pharmacist may delegate the administration of immunizations to another person, except for a licensed intern who has completed training as prescribed in Utah Administrative Code R156-17b-621 of the Pharmacy Practice Act Rules and who is practicing under the direct supervision of a pharmacist who has completed training as prescribed in Utah Administrative Code R156-17b-621 of the Pharmacy Practice Act Rules.

The pharmacy shall post in a prominent place an emergency plan to be implemented in case of an adverse event. Such plan shall include: the phone number of the local EMS, and the roles of the pharmacist and other participants.

In the course of treating adverse events following immunization, the pharmacist is authorized to administer:

-epinephrine (at a dose of approximately 0.01mg/kg body weight; maximum of 0.5mg per dose) and

-diphenhydramine (at a dose of approximately 1.0mg/kg; maximum dose of 50-100mg per dose) by appropriate routes pending availability of emergency medical services.

The pharmacist may provide cardiopulmonary resuscitation as needed.

For adverse events the pharmacist shall complete and submit the Vaccine Adverse Event Reporting System (VAERS) form to the CDC and the patient's primary care practitioner, if known.

In the course of immunizing, the pharmacist must maintain perpetual records of all immunizations administered including patient name; primary care practitioner (if known); vaccination date; name, address, title of pharmacist administering; name of vaccine; manufacturer; lot number. Before immunization, all vaccine candidates will be questioned regarding previous adverse events after immunization, food or drug allergies, current health conditions, recent receipt of blood or antibody products, immunosuppression, pregnancy, and underlying diseases. All vaccine candidates will be informed of the specific benefits and risks of the vaccine(s) offered.

Pharmacist(s) shall report administered vaccines to the Utah State Immunization Information System (USIIS) electronic registry. Updates to the USIIS registry will be completed within one week of any vaccine administered. Register for USIIS: http://www.usiis.org/howtoparticipate_provider.shtml

Summary of Discussion at June 6 meeting of SB 55 Task Force

Mr. Oborn summarized key elements of SB 55. In short, the bill created two licenses: dispensing medical practitioner (DMP) and dispensing medical practitioner (DMP) clinic pharmacy. The bill defined a DMP clinic pharmacy as a closed door pharmacy. For this reason, the Division classifies it as Class B pharmacy. SB 55 makes it possible for the following DMP clinics to dispense certain drugs if licensed by the Division:

- Cosmetic drug dispensing clinics
- Injectable drug dispensing clinics (HCG)
- Cancer drug regimen clinics
- Employee sponsored clinics

There is a question of which Class B pharmacy standards under the current Pharmacy Practice Act Rule found in Utah Admin. Code R156-17b should not apply to DMP clinic pharmacies. Members of the task force agreed that it made sense to separate DMP clinic pharmacies into two groups within the Class B pharmacy classification:

- B1: Prepackaging. A pharmacy performs prepackaging services in the sense that it relabels the original container received from the manufacturer.
- B2: Repackaging. A pharmacy performs repackaging services in the sense that it removes pills from an original manufacturer container, separates them into a smaller amount, and places them in a separate container.

Members of the task force identified multiple standards that apply to current closed Class B pharmacies that should not apply to the B1 group. These included requirements for a sink, security system that detects entry, and other requirements. Mr. Oborn indicated that the Division is willing to consider the possibility of changing some standards for Class B pharmacies in all subcategories, not just the new DMP clinics. Mr. Oborn will obtain input from the Board of Pharmacy regarding this possibility at the next Board of Pharmacy meeting on Tuesday, June 24.

Mr. Oborn indicated that the Division will post license applications for the DMPs and DMP clinics on the Division website on July 1, 2014. There will be a soft enforcement of the new licensing law, meaning that the Division will provide DMPs and DMP clinics time to get licensed beyond the July 1, 2014 effective date of the new law. The Division has not yet determined how long this grace period will last. Mr. Oborn indicated that it would last at least until after the new rules become effective. The deadline to file the proposed rules is November

2014.

The task force will meet again on Thursday, July ⁹~~10~~ at 8:30 A.M - 11:30 A.M. to further discuss the standards to which DMPs and DMP clinic pharmacies will be subject to under R156-17b. The meeting will be held in Room 474 in the Heber M. Wells Building located at 160 E 300 S in SLC.

58-17b-613. Patient Counseling

- (1) A retail pharmacy shall verbally offer to counsel a patient or a patient's agent in a personal face-to-face discussion regarding each prescription drug dispensed, if the patient or patient's agent:
 - (a) delivers the prescription in person to the pharmacist or pharmacy intern; or
 - (b) receives the drug in person at the time it is dispensed at the pharmacy facility.

- (2) A pharmacist or pharmacy intern at a pharmacy that receives a prescription from a patient by means other than personal delivery, and that dispenses prescription drugs to the patient by means other than personal delivery, shall:
 - (a) provide patient counseling to a patient regarding each prescription drug the pharmacy dispenses; and
 - (b) provide each patient with a toll-free telephone number by which the patient can contact a pharmacist or pharmacy intern at the pharmacy for counseling.

- (3) Notwithstanding the provisions of Subsections (1) and (2), a pharmacist or a pharmacy intern may provide patient counseling to an individual under the jurisdiction of the Utah Department of Corrections or a county detention facility via a written, telephone, or electronic communication.

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 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.
- (4) The offer to counsel shall be documented and said documentation shall be available to the Division. These records shall be maintained for a period of five years and be available for inspection within 7-10 business days.
- (5) Only a pharmacist or pharmacy intern may orally provide counseling to a

patient or patient's agent and answer questions concerning prescription drugs.

- (6) If a prescription drug order is delivered to the patient or the patient's agent at the patient's or other designated location, the following is applicable:
 - (a) the information specified in Subsection (1) of this section shall be delivered with the dispensed prescription in writing;
 - (b) if prescriptions are routinely delivered outside the area covered by the pharmacy's local telephone service, the pharmacist shall place on the prescription container or on a separate sheet delivered with the prescription container, the telephone number of the pharmacy and the statement "Written information about this prescription has been provided for you. Please read this information before you take this medication. If you have questions concerning this prescription, a pharmacist is available during normal business hours to answer these questions."; and
 - (c) written information provided in Subsection (6)(b) of this section shall be in the form of patient information leaflets similar to USP-NF patient information monographs or equivalent information.
- (7) Patient counseling shall not be required for inpatients of a hospital or institution where other licensed health care professionals are authorized to administer the patient's drugs.

23. Patient Counseling Requirements

State	Is Patient Counseling Required for:				Must Patient Counseling be Performed Personally, Face-to-Face, by the Pharmacist?	Are Patient Profiles Mandated?
	Medicaid Patients?	All Other Patients?	New Prescriptions?	Refill Prescriptions?		
Alabama	Yes Z	Yes Z	Yes Z	A	Yes Z	Yes
Alaska	Yes	Yes	Yes	No	Yes C	No
Arizona	Yes	Yes	Yes	Yes D	Yes	Yes
Arkansas	Yes	Yes	Yes	E	Yes B	Yes
California	Yes	Yes	Yes	No E	No I	Yes
Colorado	Yes	No	No	No	No	No
Connecticut	Yes	No	Yes G	No	Yes C, G	Yes
Delaware	Yes H	Yes H	Yes H	No	Yes C	Yes
District of Columbia	Yes	Yes	Yes	No AA	Yes L	Yes
Florida	H	H	H	H	Yes I	Yes
Georgia	Yes	Yes	Yes	No	Yes C	Yes
Guam	Yes	Yes	Yes	No	Yes	No
Hawaii	Yes J	No	J	J	Yes	Yes
Idaho	Yes	Yes	No BB	No	Yes Y	Yes
Illinois	H	H	H	H	Yes I, M	Yes
Indiana	H	H	H	H	Yes A, L, O	Yes
Iowa	Yes	Yes	Yes	No	No N	Yes
Kansas	Yes	Yes	Yes	No E	Yes B	Yes
Kentucky	Yes	Yes	Yes	No	Yes B	Yes
Louisiana	Yes	Yes	Yes M	Yes M	Yes B, M	Yes A
Maine	Yes	Yes	Yes	H	Yes	Yes
Maryland	Yes	No	Yes	No	No	No
Massachusetts	H	H	H	E	Yes I	Yes
Michigan	Yes	Yes	Yes	E	Yes O	Yes A
Minnesota	Yes	Yes	Yes	Yes E	Yes	Yes
Mississippi	Yes	Yes A	Yes A	Yes A	Yes B	Yes
Missouri	Yes	Yes	Yes	Yes	Yes P	Yes
Montana	Yes	Yes	Yes	E	Yes K	Yes
Nebraska	Yes H	Yes H	Yes H	Yes H	No	Yes
Nevada	Yes	Yes	Yes	E	Yes I, K	Yes
New Hampshire	Yes	Yes	Yes	No	Yes B	Yes
New Jersey	Yes	Yes	Yes	No	Yes K	Yes
New Mexico	Yes	Yes	Yes	Yes X	Yes K	Yes
New York	Yes	Yes	Yes W	Yes W	Yes A, K	Yes
North Carolina	Yes	Yes	Yes L	E	Yes	Yes
North Dakota	Yes	Yes	Yes	Yes	Yes	Yes
Ohio	Yes H	Yes H	Yes H	Yes H	Yes I, L	Yes
Oklahoma	Yes A	Yes A	E	E	Yes	Yes
Oregon	Yes	Yes	Yes	Yes O	Yes B	Yes
Pennsylvania	Yes	Yes	Yes	No	Yes A	Yes
Puerto Rico	Yes	Yes	Yes	Yes	Yes	U
Rhode Island	Yes H	Yes H	Yes H	No	Yes K, L	Yes
South Carolina	Yes R	No H	No H	No	No B	Yes
South Dakota	Yes	Yes	Yes	No	Yes B, N	Yes
Tennessee	Yes	Yes	Yes	Yes H	Yes	Yes
Texas V	Yes	Yes	Yes	Yes S	Yes S	Yes
Utah	Yes	Yes CC	Yes CC	Yes CC	Yes I	Yes
Vermont	Yes H, P	Yes H, P	Yes H, P	Yes H, P	Yes O	Yes
Virginia	Yes	Yes	Yes	E	Yes B	Yes T
Washington	Yes	Yes	Yes	E	Yes B	Yes
West Virginia	H	H	H	E	Yes M	Yes
Wisconsin	Yes	Yes	Yes	Yes	Yes F	Yes
Wyoming	H	H	H	No	Yes B	Yes

Colored text denotes change from 2013 edition.

LEGEND

- A — When applicable/appropriate. (AL — Only when appropriate in judgment of a registered pharmacist.)
- B — Face-to-face if prescription is delivered to the patient within the pharmacy; otherwise, by telephone or in writing. Required for all new prescriptions and as appropriate for refills. (KY — Required for all original prescriptions and as appropriate for refills. LA and SC — Face-to-face when possible, otherwise by alternative method.)
- C — Whenever practicable. (AK — When not possible, pharmacist must make reasonable effort to counsel by telephone, two-way radio, or in writing.)
- D — With different directions, dose, or dosage form.
- E — The pharmacist can use professional judgment in deciding whether or not to counsel.
- F — Although face-to-face counseling is not required, the pharmacist must personally counsel the patient.
- G — For Medicaid patients.
- H — Only an offer to counsel is required. (SC — On new medication.)
- I — Face-to-face if prescription is delivered to the patient or patient's agent within the pharmacy; otherwise, a written offer to counsel with toll-free telephone access to a pharmacist must be made. (CA — For prescriptions dispensed out-of-state.)
- J — Omnibus Budget Reconciliation Act requirements under the jurisdiction of the Department of Human Services, Health Care Authorization Branch.
- K — In person, whenever practicable, or by telephone. (MT — Shall include appropriate elements of patient counseling. NM — If the patient or agent is not present when the prescription is dispensed, including but not limited to a prescription that was shipped by mail, the pharmacist shall ensure that the patient receives written notice of his or her right to consultation and a telephone number to obtain oral consultation from a pharmacist. Required for all new and refill prescriptions. NV — May also be in writing if the patient or caregiver is not present at the pharmacy. NY — If the patient or agent is not present when the prescription is dispensed; toll-free number required.)
- L — The offer to counsel may be delegated by the pharmacist to non-licensed personnel. The actual counseling must be performed by the pharmacist or pharmacist intern/extern. (IN — May be delegated to other pharmacy personnel. DC — The consultation shall be face to face, whenever practicable, or by telephone. The consultation shall be reinforced with the provision of written information, which may include information leaflets, pictogram labels, or video programs.)
- M — Unless pharmacist deems counseling inappropriate or unnecessary, in which case it may be written, by telephone, or as considered appropriate.
- N — If oral counseling is deemed not practicable, alternate forms of patient information may be used, which also advise patient or caregiver that pharmacist is available for consultation at pharmacy, via toll-free telephone number or collect call. Combination of oral and alternative forms of counseling is encouraged. (IA — The mere offer to counsel is not sufficient.)
- O — In person to patient or patient's caregiver; if communication barrier prohibits oral communication, then providing printed material. (IN — May counsel patient's representatives.)
- P — The offer to counsel may be delegated by the pharmacist to technical personnel. The actual counseling must be performed by the pharmacist or pharmacist extern (only under supervision of a pharmacist).
- Q — Counseling on refill prescriptions shall be such as a reasonable and prudent pharmacist would provide including but not limited to changes in strength or directions. A pharmacist may provide counseling in a form other than oral counseling when, in their professional judgement, a form of counseling other than oral counseling would be more effective. For a discharge prescription from a hospital, the pharmacist must ensure that patient receives appropriate counseling.
- R — Health and Human Services Finance Commission Regulation.

*Legend continued on page 83***NABPLAW Online Search Terms****Patient Counseling Requirements***(type as indicated below)*

- ◆ advise patient
- ◆ inform patient
- ◆ patient counseling requirements
- ◆ patient profile
- ◆ prescription counsel
- ◆ refill counsel

23. Patient Counseling Requirements (cont.)

2014

LEGEND — cont.

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| S | — | Face-to-face if prescription is delivered to the patient within the pharmacy; otherwise in writing. Required for all new prescriptions, pharmacist or agent must make an offer to counsel on all prescription refills and in the professional judgment of the pharmacist for all other refills. | X | — | Offer to counsel on a refill may be made by a registered technician. |
| T | — | Not specifically called "patient profile." | Y | — | When possible or appropriate. |
| U | — | Not specifically addressed in Pharmacy Act or regulations. | Z | — | An offer to counsel is mandatory. The offer must be face-to-face unless in the professional judgement of the pharmacist face-to-face counseling is inappropriate or unnecessary and in that situation, the offer to counsel may be in writing, by telephone, or in any other manner deemed appropriate by the pharmacist. |
| V | — | Pharmacy must post a sign informing patients that a pharmacist is available to answer questions about prescription medications. | AA | — | Once yearly on maintenance medications. See DCMR 22 1919.1(c). |
| W | — | A pharmacist or intern must counsel on all new prescriptions or when a regimen is changed. Anyone under the direction of a pharmacist may make an offer to counsel on refills. | BB | — | New medications only. |
| | | | CC | — | Offer to counsel required on all new prescriptions, once yearly on maintenance medication. |

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