



# Utah Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

PO Box 146741 • Salt Lake City, UT 84114-6741  
[www.dopl.utah.gov/licensing/pharmacy.html](http://www.dopl.utah.gov/licensing/pharmacy.html)

## 2014 Utah General Legislative Session

It was a busy legislative session as the Utah State Legislature passed several bills that impact pharmacy practice. A summary of bills impacting pharmacy practice is provided in the paragraphs below. You may access a full copy of individual bills at [www.le.utah.gov](http://www.le.utah.gov). The effective dates for these bills are contingent upon Governor Gary Herbert's right to veto. Some amendments require drafting of administrative rules to be adopted by the Utah Department of Commerce.

**HB 114: Mail-Order Wholesale Drug Amendments.** Utah is the 48<sup>th</sup> state to require pharmacy licensure for nonresident pharmacies that engage in the manufacture, production, wholesale, or distribution of drugs. In the past, mail-order pharmacies mailing directly to patients were the only pharmacies located outside Utah that were required to have Utah licenses. **Effective July 1, 2014.**

### SB 55: Pharmaceutical Dispensing Amendments

- ◆ **Drug Sales Between Pharmacies.** A pharmacy in Utah not licensed specifically as a pharmaceutical wholesaler or distributor may sell drugs to other pharmacies if their total distribution-related sales of prescription drugs do not exceed 5% of the facility's total prescription drug sales. **Effective July 1, 2014.**
- ◆ **Hospital Pharmacy Dispensing of Multidose Drugs to Discharged Patients.** A hospital pharmacy may dispense a prescription drug in a multidose container to a hospital patient being discharged if labeling requirements outlined in the bill are met. **Effective July 1, 2014.**
- ◆ **License Classification for Dispensing Medical Practitioners and Clinics.** A new license classification titled "dispensing medical practitioner" was created for medical practitioners who prescribe and dispense certain drugs. A pharmacy facility license classification titled "dispensing medical practitioner clinic pharmacy" was created for clinics that dispense certain drugs in limited settings. Creating these licenses required removal of the license exemption of medical practitioners and clinics for medical practitioners who prescribe and dispense a cosmetic drug, injectable weight loss drug, or a cancer drug treatment regimen. A medical dispensing practitioner's ability to dispense is limited to a cosmetic drug, a cancer drug treatment regimen,

or a prepackaged drug at an employer-sponsored clinic. It establishes that practice as a dispensing medical practitioner does not include the use of a vending-type dispensing device or the dispensing of controlled substances (CS), except for the dispensing of Schedule IV and V CS as permitted for cancer drug treatment regimens. **Effective July 1, 2014.**

- ◆ **Clarification of Acceptable Methods of Drug Delivery.** A pharmacy may only deliver a prescription drug to a patient or patient's agent in person at the pharmacy. It may also deliver a prescription drug via the United States Postal Service, a licensed common carrier, or supportive personnel, if the pharmacy takes reasonable precautions to ensure the prescription drug is (1) delivered to the patient or patient's agent or (2) returned to the pharmacy. **Effective July 1, 2014.**
- ◆ **Clarification of Patient Counseling Standards.** Patient counseling standards were clarified to address misunderstandings caused by prior statutory language. **Effective July 1, 2014.**

### SB 77: Pharmacy Practice Act Amendments

- ◆ **Creation of Pharmacy Technician Trainee License.** Before working in a pharmacy, a pharmacy technician-in-training is now required to obtain a "pharmacy technician trainee" license from the Utah Division of Occupational and Professional Licensing (Division). To apply for a pharmacy technician trainee license, individuals must submit a license application to the Division including a criminal background check and the name of their training program. **Effective July 1, 2014.**
- ◆ **Pharmacy Selling of Drugs to Practitioners for Office Use.** Pharmacies may repackage or compound a prescription drug for sale to a practitioner under circumstances outlined in the bill. **Effective July 1, 2014.**

**SB 78: Prescription Eye Drop Guidelines.** A pharmacist or pharmacy intern may dispense a refill of a prescription for a liquid legend drug administered to the eye once an amount of time has passed after which a patient should have used 70% of the dosage units of the drug according to a practitioner's instructions. **Effective May 13, 2014.**

*continued on page 4*



## **New USP Webpage Answers Common Questions About USP Chapters <795> and <797>**

In response to questions concerning United States Pharmacopeia-National Formulary (USP-NF) General Chapters <795> and <797>, USP has created a new frequently asked questions (FAQs) page on its website. The FAQs answer questions related to the Revision Bulletin for Chapter <795> that was issued on November 22, 2013, and became official on January 1, 2014. Among other topics, the FAQs address common questions regarding beyond-use dating and the differences between testing stability with strength (potency) or stability-inducing methods. The FAQs can be accessed at [www.usp.org/support-home/frequently-asked-questions/compounding](http://www.usp.org/support-home/frequently-asked-questions/compounding). Question four on the page includes a link to a USP article, "Strength and Stability Testing for Compounded Preparations."

## **Only You Can Prevent Look-Alike Sound-Alike Drug Names**

 *This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting [www.ismp.org](http://www.ismp.org). ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Error Reporting Program. Report online at [www.ismp.org](http://www.ismp.org). E-mail: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org).*

**VESicare/Vesanoid Mix-Up.** A prescriber's office sent an electronic prescription to the patient's pharmacy; the prescriber intended to prescribe **VESicare**® (solifenacin succinate) for overactive bladder but inadvertently selected **Vesanoid**® (tretinoin), which is used to induce remission of acute promyelocytic leukemia. The pharmacy technician entered the prescription for generic tretinoin; however, the pharmacy was unable to dispense the medication as the patient's pharmacy benefit manager required a prior authorization. The technician faxed a request and the prescriber's office replied back that **VESicare** was intended. Both of these products are available in 10 mg solid oral dosage forms, increasing the risk of confusion. Investigate strategies (eg, tall man letters) to differentiate these products on computer screens. Prescribers should include the indication for the drug with the prescription. As always, providing patient education, especially for new prescriptions, is a good strategy to intercept errors before they impact the patient.

**Benazepril Confused With Benadryl.** A pharmacist reported a mix-up between benazepril (**Lotensin**®) and **Benadryl**® (diphenhydramine). A patient faxed a request to the pharmacy to ask for her "benazpryl." The pharmacist who received the fax interpreted

it as **Benadryl** and placed a bottle of diphenhydramine in the bag for pick-up. Around this same time, the pharmacy went through a change in wholesaler and many manufacturers of generic products were changed. A few days later, a coworker of the patient picked up the medication (along with several others). The technician at the point-of-sale told the coworker that many of the manufacturers had changed recently and that some of the pills may look different. The patient received the diphenhydramine, filled her medication box with the capsules, and took diphenhydramine daily for three weeks before noticing she was unusually tired. When she brought the bottle back to the pharmacy, the error was recognized.

ISMP continues to receive reports of confused drug name pairs being involved in errors. ISMP wants to inform its readers of these drug name confusions so they may continue evaluating what measures they have in place to protect against these possible confusions.

**Your Help Is Needed With Product Safety Testing.** If you are a pharmacist, nurse, pharmacy technician, or other health care practitioner who is interested in furthering medication safety and error prevention, you can make a difference! **Med-ERRS** (a subsidiary of ISMP) is looking for assistance to help evaluate medication labels, drug packaging, and proposed drug names prior to submission by pharmaceutical and biotech companies for approval by Food and Drug Administration (FDA). The process is fun, simple, and easy. A small honorarium is paid. For more information or to sign up, visit [www.med-errs.com](http://www.med-errs.com) and click on "Become a Reviewer."

## **FDA Issues Alert on Acetaminophen Products**

In light of all the recent news alerts and warnings about the use of acetaminophen and acetaminophen-containing products, FDA issued a recommendation of importance to pharmacists, prescribers, and patients.

FDA recommends that health care providers consider prescribing combination drug products that contain 325 mg or less of acetaminophen. FDA also recommends that when a pharmacist receives a prescription for a combination product with more than 325 mg of acetaminophen per dosage unit that he or she contacts the prescriber to discuss a product with a lower dose of acetaminophen. A two-tablet or two-capsule dose may still be prescribed, if appropriate. In that case, the total dose of acetaminophen would be 650 mg (the amount in two 325 mg dosage units). When making individual dosing determinations, health care providers should always consider the amounts of both the acetaminophen and the opioid components in the prescription combination drug product.

FDA, in its MedWatch Safety Alert, reports that, "There are no available data to show that taking more than 325 mg of acetaminophen per dosage unit provides additional benefit that outweighs the added risks for liver injury. Further, limiting the amount of acetaminophen per dosage unit will reduce the risk of severe liver injury from inadvertent acetaminophen overdose, which can lead to liver failure, liver transplant, and death."

In January 2011, FDA asked manufacturers of prescription combination drug products containing acetaminophen to limit the amount of acetaminophen to no more than 325 mg in each tablet or capsule by January 14, 2014. FDA requested this action to protect consumers from the risk of severe liver damage that

Compliance News to a particular state or jurisdiction should not be assumed as representing the law of such state or jurisdiction.)



can result from taking too much acetaminophen. More than half of manufacturers have voluntarily complied with FDA's request. However, some prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit remain available. In the near future, FDA intends to institute proceedings to withdraw approval of prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit that remain on the market.

Boards of pharmacy have received inquiries from pharmacists about remaining stock of the higher dose acetaminophen and what procedures should be followed. The FDA recommendation notes that pharmacists are advised to contact prescribers and request a change in the prescription. If the prescriber is not willing to make the change in the prescription, unfortunately, there is no clear cut recommendation at this point as to whether to dispense the higher dose acetaminophen product. It would appear that the higher dose acetaminophen-containing products will be regarded by FDA as unapproved and delisted from FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book." Until this occurs, pharmacists must make a judgment regarding continuing to dispense the higher dose acetaminophen containing products in light of the FDA recommendation and concern for patient safety.

## Some Rohto Eye Drops Products Recalled

The Mentholatum Company of Orchard Park, NY, has issued a voluntary recall of some Rohto® eye drop products due to a manufacturing review at the production facility in Vietnam involving sterility controls. The recall has been issued at the retail level and includes Rohto Arctic, Rohto Ice, Rohto Hydra, Rohto Relief, and Rohto Cool eye drops that were manufactured in Vietnam. Products made in other facilities are not affected by the recall. To date, there has been no evidence indicating the recalled products do not meet specifications, according to a press release.

The recalled products are sold over the counter at pharmacies and retail stores throughout the United States, and can be identified by the words "Made in Vietnam" on the side carton panel under the company name and address information as well as on the back label of the bottle. Lot numbers for the recalled products contain the letter "V." Distributors and retailers are being notified by letter to stop distributing the products and to follow the recall instructions provided by the company. Questions about the recall can be directed to The Mentholatum Company at 877/636-2677, Monday through Friday, 9 AM to 5 PM Eastern Time. FDA urges consumers and health care providers to report any adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information and Adverse Event Reporting Program. More information is available at [www.fda.gov/Safety/Recalls/ucm382076.htm](http://www.fda.gov/Safety/Recalls/ucm382076.htm).

## FDA Provides Compounding Law Implementation Information

FDA has provided implementation information on Title I of the recently passed Drug Quality and Security Act – known as the Compounding Quality Act – through its website.

Of note, FDA specifies that compounding entities may register as an outsourcing facility, which, under certain conditions, may be exempt from the Federal Food, Drug, and Cosmetic Act's (FD&C Act) approval and labeling requirements. Drugs produced by compounders that are not registered as outsourcing facilities must meet the conditions of Section 503A of the FD&C Act, which was amended by the new law, to qualify for certain exemptions.

The document adds, "If a compounded drug does not qualify for exemptions under either section 503A or 503B of the [FD&C Act], the compounded drug would be subject to all of the requirements of the [FD&C Act] that are applicable to drugs made by conventional manufacturers, including the new drug approval and adequate directions for use requirements." FDA also notes it will provide additional information about how the agency will interpret certain provisions of Section 503A at a later date.

The implementation information may be viewed at [www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm375804.htm](http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm375804.htm).

## New e-LTP Fees Effective July 1, 2014

Supporting ongoing efforts to protect the integrity of its licensure transfer programs and to support the expansion of new technologies that are being implemented to enhance the program, the National Association of Boards of Pharmacy® (NABP®) is adjusting the fees for the Electronic Licensure Transfer Program® (e-LTP™).

Beginning July 1, 2014, the e-LTP fees will be adjusted as follows:

- ◆ The preliminary application and first state transfer fee will increase from \$350 to \$375
- ◆ Each additional state transfer will increase from \$50 to \$75
- ◆ Change of states will increase from \$50 to \$75
- ◆ Time extensions will increase from \$50 to \$75

The fees for e-LTP were last adjusted in 2010. More information about e-LTP is available in the Programs section of the NABP website at [www.nabp.net](http://www.nabp.net). Additional questions about the fee adjustment may be directed to Neal Watson, licensure programs manager, at 847/391-4406, or at [nwatson@nabp.net](mailto:nwatson@nabp.net).



**Pharmacists & Technicians:**  
Don't Miss Out on Valuable CPE Credit.  
Set Up Your NABP e-Profile and Register for CPE Monitor Today!

Continuing pharmacy education (CPE) providers who are accredited by the Accreditation Council for Pharmacy Education (ACPE) have integrated CPE Monitor® into their systems and are requiring pharmacists and pharmacy technicians to provide an NABP e-Profile ID number and date of birth (MMDD) in order to process ACPE-accredited CPE credit.

Visit [www.MyCPEmonitor.net](http://www.MyCPEmonitor.net) to set up your NABP e-Profile and register for CPE Monitor and avoid possible delays in your CPE reporting.

*CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their completed CPE credit electronically.*

**SB 210: Prescription Synchronization Amendments.** A cap is placed on the co-pay charged by a health insurance plan for the dispensing of certain prescription drugs in quantities less than a 30-day supply. The following health insurance plans are prohibited: (1) one that provides prescription drug coverage from excluding prescription drugs dispensed in quantities less than a 30-day supply and (2) one that bases the dispensing fee for an individual prescription on the quantity of the prescription drug dispensed to fill or refill the prescription. These standards apply to health benefit plans renewed or entered into on or after January 1, 2015. **Effective May 13, 2014.**

**SB 178: CSD Modifications.** A pharmacist-in-charge (PIC) may designate up to three pharmacy technicians to have access to the Utah Controlled Substance Database Program (CSD) on behalf of the PIC under conditions outlined in the bill. **Effective May 13, 2014.**

**SB 138: Controlled Substances Act Amendments.** More than one CS may be included on a prescription for a Schedule III through V drug. A prescription to contain a legend drug may be included on the same prescription. **Effective May 13, 2014.**

**HB 113: Pharmacy Benefit Manager Amendments.** Certain reimbursement practices of pharmacy benefit managers are regulated. The bill defines maximum allowable costs, requires certain contract provisions between a pharmacy benefit manager and a pharmacy related to the use of maximum allowable cost and appeal rights, and requires a pharmacy benefit manager to register with the Division of Corporations and Commercial Code within the Utah Department of Commerce. **Effective May 13, 2014.**

**HB 119: Opiate Overdose Emergency Treatment.** Dispensing of an opiate antagonist is permitted to a person who is reasonably believed to be at risk of experiencing an opiate-related drug overdose event. It is not unlawful or unprofessional conduct for health professionals to prescribe an opiate antagonist to a person at increased risk of an overdose or a family member, friend, or other person who would be able to assist in an overdose. The ability to administer the opiate antagonist does not establish a duty to act. Finally, the health professional will advise the person to seek help after an overdose and opiate antagonist administration. **Effective May 13, 2014.**

## **Recent Rule Amendments**

**New Pharmacy Technician Training Program Requirements.** Under SB 194, passed during the 2013 Legislative Session, and rule amendments to Utah Administrative Code R156-17b-303a, all pharmacy technician training programs must be accredited by the American Society of Health-System Pharmacists (ASHP) or conducted by the National Pharmacy Technician Association (NPTA). Existing programs without ASHP or NPTA approval, but approved by the Division before March 31, 2014, will continue to meet the program requirement until January 1, 2016. Beginning January 2, 2016, all programs must be accredited by ASHP or conducted by NPTA. **Effective December 23, 2013.**

**Pharmacies Required to Comply With USP-NF Chapter 17 Labeling Standards.** Under rule amendments to Utah Administrative Code R156-17b-402 (24), it is unprofessional conduct for a pharmacy or pharmacist to fail to comply with

prescription container label standards established in United States Pharmacopeia-National Formulary (USP-NF) Chapter 17. Most pharmacies and pharmacists currently comply with these standards; however, those who currently do not have until November 30, 2014, to comply. **Effective December 23, 2013.**

## **Division Pharmacy Investigation Report**

The Division completed the 2013 self-inspection audit and is pleased that most pharmacies responded. The Division sent out 480 self-inspection audits. In response to the audits, the Division issued approximately 40 letters of concern and two citations. The Division appreciates the diligent efforts of Utah pharmacies to maintain compliance with required standards. Laws outlining the Division's authority to conduct pharmacy investigations include the following:

Utah Code 58-17b-103. Administrative Inspections.

- (1) The division may for the purpose of ascertaining compliance with the provisions of this chapter, require a self-audit or enter and inspect the business premises of a person:
  - (a) licensed under Part 3, Licensing: or
  - (b) who is engaged in activities that require a license under Part 3, licensing. . .

This section grants the Division two options for completing administrative inspections: a self-audit completed by the pharmacy or a Division inspection of the facility. When a self-inspection audit is needed, information is sent via e-mail to pharmacies, along with any other information that the Division deems important. This includes various types of pharmacy alerts such as warnings about persons suspected of doctor shopping. Under Utah Code 58-17b-502, the following qualifies as unprofessional conduct for a pharmacy: failing to return or providing false information on a self-inspection report; failing to provide PIC information to the Division within 30 days of a change in PIC; and failing to update the Division within seven calendar days of any change in the e-mail address designated for use in self-audits or pharmacy alerts. If you have any questions or input regarding pharmacy investigations, please contact the Division's Bureau of Investigation at [doplinvestigations@utah.gov](mailto:doplinvestigations@utah.gov) or 801/530-6326.

## **Upcoming Board Meetings**

Upcoming meetings of the Utah Board of Pharmacy are scheduled for April 22, May 27, June 24, and July 22. Most meetings are held in Room 474 on the fourth floor of the Heber M. Wells Building located at 160 East 300 South in Salt Lake City, UT. Meetings typically begin at 8:30 AM.

---

Page 4 – April 2014

The *Utah Board of Pharmacy News* is published by the Utah Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation, the State of Utah, or the Board unless expressly so stated.

Utah Board of Pharmacy - State Newsletter Editor  
[doplbureau3@utah.gov](mailto:doplbureau3@utah.gov)

[www.dopl.utah.gov/licensing/pharmacy.html](http://www.dopl.utah.gov/licensing/pharmacy.html)

Carmen A. Catizone, MS, RPh, DPH - National News Editor & Executive Editor

Deborah Zak - Communications Manager

---