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Idaho State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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Pharmacy Statutory Changes

The following statutory changes have passed the 2014 Idaho Legislature and have been signed by the honorable C.L. "Butch" Otter, governor of the state of Idaho. The effective date of these changes is July 1, 2014.

In response to Idaho State Board of Pharmacy orders that disciplined prescribers for diversion, **54-1754. Restriction on Transactions** now includes the following requirement: "A manufacturer or wholesale distributor shall only furnish a scheduled controlled substance . . . to a person who has been issued a valid controlled substance registration by the United States drug enforcement administration and the Idaho board of pharmacy."

In response to a request from the Board's Pharmacist Recovery Network (PRN) administrator, Southworth Associates, so that Southworth Associates may obtain prescription monitoring program (PMP) data on PRN enrollees, **37-2726. Filing Prescriptions–Database** has been amended to require that: PMP "data base information must be made available to: . . . An individual who is the recipient of a dispensed controlled substance entered into the database may access records that pertain to that individual, upon identification, or that individual's designee upon production of a notarized release of information by that individual."

This bill was not run by the Board, but it was run with the support of the Board, pursuant to these changes to the Idaho Pharmacy Act: **33-520A. Life Threatening Allergies in Schools:** "Any physician, advanced practice registered nurse licensed to prescribe or physician assistant licensed to prescribe . . . may prescribe epinephrine auto-injectors in the name of a school. . . Licensed pharmacists and physicians may dispense epinephrine auto-injectors pursuant to a prescription issued (as such)." **54-1733. Validity of Prescription Drug Orders:** "A prescriber . . . may prescribe or perform any of the following activities for a patient with whom the prescriber does not have a prescriber-patient relationship under the following circumstances: . . . Epinephrine auto-injectors in the name of a school pursuant to section 33-520A, Idaho Code." **54-1734. Exceptions:** "The provisions of this chapter pertaining to the sale of prescription drugs are not applicable . . . to the possession of legend drugs by such persons or their agents or employees for such use. . . Schools possessing stock supplies of epinephrine auto-injectors pursuant to section 33-520A, Idaho Code." Please note that the statutory requirement to label in the name of the patient was also struck and will be further clarified by rule in 2015.

Pursuant to recent Drug Enforcement Administration (DEA) scheduling activity, but expanding the category of covered designer illicit substances in Idaho, the following changes have been made:

- **37-2705: Schedule I:** Several hallucinogenic substances that are generally referred to as designer modifications of ecstasy
- **37-2709. Schedule III:** Methasterone and prostanozol
- **37-2711: Schedule IV:** Alfaxalone and lorcaserin

Compounding

As stated in the March 2014 Board *Newsletter,* pharmacies must dispense compounded drug product pursuant to a patient-specific prescription drug order. Compounded drug product that is distributed in the absence of a patient-specific prescription drug order is rendered as manufactured. In other words, both federal and state law prohibit pharmacies from distributing compounded drug products for "office use." Federal law allows for a new category of drug outlet to meet "office use" needs: the outsourcing facility. You may access a list of Food and Drug Administration-registered outsourcing facilities at the following link: *www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm378645.htm*. The Board has been enforcing such law on a priority basis and will immediately begin enforcement of such law for all sterile compounded drug product. All sterile compounded drug product must be dispensed by a pharmacy pursuant to a patient-specific prescription drug order and not distributed by a pharmacy for "office use." Prescribers and hospitals are required to obtain "office use" sterile compounded drug product from federally registered outsourcing facilities.

Refill Authorization

Rule 116.01.b states, "Refills exceeding those authorized by the prescriber on the original prescription drug order may only be authorized through issuance of a new and separate prescription drug order." Although Rule 400.03.a (Prohibited Tasks or Functions by a Technician) lists "receive a new verbal prescription drug order," an authorization to refill that is telephoned to the pharmacy by the prescriber or the prescriber's agent may be received by a technician if there are no changes to the original order. Subsequently, a new prescription drug order may be created. Any change to the original prescription must be communicated to a pharmacist.

2014-2015 Renewal Season

Pharmacists, technicians, pharmacies, and drug outlets are among the many registrants and licensees that are required to re-

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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.* 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. *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. *E-mail: 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 "benazapryl." 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* 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

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.*

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.*

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.* Additional questions about the fee adjustment may be directed to Neal Watson, licensure programs manager, at 847/391-4406, or at nwatson@nabp.net.

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new by June 30, and should have already received a renewal form or a bright yellow postcard with online renewal instructions. The Board has successfully implemented online renewals for 99% of its licensees and registrants. Online renewal is not required, but it is strongly encouraged. You may now renew online but still pay with a check by simply printing out your completed renewal and sending it in with payment. Paper forms are available by contacting the Board office. Late fees are imposed on July 1, and if not renewed by July 31, licenses and registrations will be required to be reinstated, which includes fingerprinting for pharmacists and technicians. Licensees and registrants may be subject to discipline if practicing without the proper license or registration. The online renewal process also allows for the reporting of changes to initial or prior renewal applications, if not already in compliance with Rule 017.06, which requires the Board to be notified within 10 days of such changes. For questions or if encountering complications, please contact the Board at info@bop.idaho.gov or 208/334-2356.

New Board Inspector

Replacing long-time Board inspector Gina Knittel is Tanya Conner, who will be stationed in northern Idaho. Ms Conner has 14 years' experience as a pharmacy technician, during which she has worked in retail, hospital, long-term care, and mail service pharmacy. The Board welcomes an inspector with sterile compounding experience. Ms Conner will be attending the National Association of Boards of Pharmacy® sterile compounding inspector training this fall.

Future Board Meetings

The following dates and locations are subject to change. Meeting times are yet to be determined. Please check the Board's website for potential updated information.

August 14 at the State Capitol Building, Room WW53, Boise, ID. At this meeting, a negotiated rulemaking session will be scheduled to receive public comment on the Board's draft 2015 rule and statute changes. Said changes are expected to be published on the Board's website at least one week earlier.

October 22 and 23 at a location to be determined in Boise. October 23 will be the last day of the official open public comment period on the Board's proposed rules that print in the October *Idaho Administrative Bulletin* and will be available on the Board's website in September. The Board will take public comment on October 23 and deliberate upon it on October 24.

Recent Board Discipline

C.S., Technician-in-Training: Registration revoked for diversion.

A.M., Pharmacy Technician: Registration revoked for diversion.

C.W., Pharmacy Technician: Registration revoked for diversion.

D.H., RPh: License and controlled substance (CS) registration revoked for diversion.

T.R., RPh: License and CS registration suspended, $1,000 fine, and mandatory PRN compliance for diversion.

R.S., RPh: License and CS registration suspended, mandatory PRN compliance, and $2,000 fine for felony conviction.

L.M., RPh: License and CS registration revoked for failure to comply with an order of the Board.

I.C., RPh and Pharmacist-in-Charge: Fined $3,000 for failure to renew CS registration and continuing to work while unregistered.

B.Z., PA: Schedule II privileges revoked pursuant to a DEA order.

R.M., MD: CS registration restricted pursuant to State of Idaho Board of Medicine order.

R.A., DDS: CS registration suspended pursuant to Idaho Board of Dentistry order.

D.W., MD: CS registration suspended pursuant to State of Idaho Board of Medicine Order.

Special Notice

The *Idaho State Board of Pharmacy Newsletter* is considered an official method of notification to pharmacies, pharmacists, pharmacy interns/externs, and pharmacy technicians registered by the Board. Please read them carefully. The Board encourages you to keep them filed in your pharmacy, preferably in your *Idaho Pharmacy Law Book,* for future reference.

The *Idaho State Board of Pharmacy News* is published by the Idaho State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation™ (NABPF™) 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 NABPF or the Board unless expressly so stated.

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