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Nevada State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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Welcome New Board Members!

Governor Brian Sandoval has appointed two new members to the Nevada State Board of Pharmacy to three-year terms that began in December 2013, and has reappointed consumer Board member Cheryl Blomstrom (from Blomstrom Consulting, Inc, and who brings invaluable regulatory insight to the Board) to a second three-year term. Congratulations to the ladies first! Joining Cheryl on the Board is Tallie Pederson of Las Vegas, NV, a Walgreen's pharmacy manager originally from Ohio and a May 2008 PharmD graduate from the University of Toledo. Sporting an infectious smile and unparalleled enthusiasm for the pharmacy profession, Tallie anxiously has delved into her new role as a Board member. The second new appointee is Kevin Desmond, the pharmacy manager of Renown South Meadows Medical Center in Reno, NV. Kevin is of the storied Desmond family; a family with a long and respected pharmacy history in Northern Nevada, including his father, Frank, the former owner of Keystone Owl Rexall Drugstore in Reno. Kevin's wife, Cathy, is a pharmacist as well. Kevin has been active in past Board activities, serving tirelessly on subcommittees on compounding and hospital regulations. Congratulations to Cheryl, Tallie, and Kevin, as Board staff wishes them productive and gratifying Board tenures.

Sadly, the appointment of new Board members means the replacement of others. Both Jody Lewis of Las Vegas and Russell Smith of Gardnerville, NV, have served the citizens of Nevada admirably throughout their Board terms, and the Board wishes them the best and sincerely thanks them for their service.

How Could I Make That Error?

Ever hear of "inattentional blindness"? It refers to the failure to see something that is not expected to be seen, like a drug utilization review alert, and it tends to be involuntary. A verifying pharmacist is not expecting a dose to be wrong and consequently is "inattentionally blinded" and does not "see" the high dose alert, overrides it, and dispenses an overdose. He or she saw what he or she expected to see as he or she looked at an order on the computer screen and mentally filled in the missing dose as it is typically ordered, even though it was incorrect.

Pharmacists must be aware of what factors contribute to inattentional blindness, those being one's capacity to pay attention (altered by lack of sleep and fatigue); one's expectation (confirmation bias); and one's mental workload (distractions, multitasking). Advice: get ample rest, focus on one task at a time, and expect the unexpected!

Roseman University of Health Sciences Student Recognized

Congratulations are in order for Roseman University of Health Sciences College of Pharmacy student Robert (Bobby) Angel who was recently named by the American Pharmacists Association (APhA) as an awardee in the 2014 *Pharmacy Today/ Student Pharmacist* One to One Patient Counseling Recognition Program. Bobby is being recognized as an outstanding student pharmacist who has performed exceptional one-to-one counseling resulting in better health, superior communication, and improved outcomes. He will receive the award in Orlando, FL, at the 2014 APhA Annual Meeting and Exposition. Kudos, Bobby!

Attention Pharmacies: Claims Adjudication Process to Validate Ordering, Prescribing, and Referring Practitioners

In order for Medicaid to reimburse for services or medical supplies that require a provider's order, prescription, or referral, the Affordable Care Act (42 CFR, Parts 405, 447, 455, 457, and 498) requires that the ordering, prescribing, or referring (OPR) provider be enrolled in Medicaid. Compliance with this requirement necessitates **future** changes to the Nevada Medicaid claims and provider enrollment processes. The Nevada Department of Health and Human Services Division of

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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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Health Care Financing and Policy is actively working on the implementation of this new requirement, which is anticipated to occur the fourth quarter of 2014.

How Will This Affect You?

The practitioner writing a prescription for a Medicaid fee-for-service recipient needs to be enrolled as a full Medicaid service provider or an OPR-only provider by the **last quarter of 2014.**

To comply with these provisions, Nevada Medicaid, with the implementation of the OPR claims adjudication process, will verify both the presence of a valid practitioner National Provider Identifier (NPI) and the practitioner's enrollment in Nevada Medicaid as either a full Medicaid service provider or an OPR-only provider. Pharmacy claims will post an edit informing the billing provider if the NPI for the prescriber is not present. If the prescriber does not have prescriptive authority, or is not enrolled as either a full Nevada Medicaid service provider or an OPR-only provider, the edit will result in a claim denial.

Every prescriber must include his or her personal NPI on each prescription. Every pharmacy must accurately submit this prescriber NPI with each prescription claim. If a provider intentionally submits a claim with a prescriber NPI that he or she knows to be inaccurate, he or she is committing a fraudulent act and may be subject to administrative, civil, and/or criminal actions.

For more information about the changes to billing and the new OPR provider enrollment category, call the Catamaran Technical Call Center at 866/244-8554.

RxPATROL – Twitter Provides New Way to Fight Pharmacy Crime

RxPATROL Tweets Crimes, Rewards, and Valuable Tips – Pharmacy staff, law enforcement officials, and loss prevention personnel can now follow updates about pharmacy robberies, burglaries, and potential threats in their area and nationwide at *http://twitter.com/rxpatrol.* The tweets provide safety and security tips for pharmacy staff that may help them better protect customers and their businesses.

Tweets contain specific information on robberies and burglaries including the exact location of the incident, description of the suspect, and any pertinent information that could lead to the capture of a suspect. All information is verified with local law enforcement before it is released. All tweets direct followers to the Rx Pattern Analysis Tracking Robberies & Other Losses (RxPATROL) database for additional information, including pictures and videos of suspects.

Purdue Pharma L.P. developed RxPATROL in 2003 as a collaborative effort among industry, pharmacists, and law enforcement to collect, collate, analyze, and disseminate information on pharmacy theft in the United States, and posts important crime-related information at *www.RxPATROL.org.* The program also issues alerts and updates via e-mail to registered users in the pharmacy and law enforcement communities. However, since many pharmacy staff members do not have Internet access during work hours but do have access to cell phones, RxPATROL is now using Twitter to instantly deliver pharmacy crime updates to followers via their cell phones.

Twitter can provide followers with timely pharmacy crime information, giving them access to information that is often not reported by the media. Twitter followers also receive notices for reward offers that are funded through Purdue Pharma L.P.'s partnership with Crime Stoppers and other local anti-crime organizations.

"Pharmacy crime is a problem in many communities," said RxPATROL Program Analyst Captain Richard Conklin. "RxPATROL is using new communication vehicles to help pharmacy staff and law enforcement fight pharmacy crime."

Conklin monitors daily pharmacy crime reports from police departments across the US and posts important crime related information on the RxPATROL website. Please visit *www.rxpatrol.org* for more information and start following RxPATROL by visiting *http://twitter.com/rxpatrol.*

The *Nevada State Board of Pharmacy News* is published by the Nevada State 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 or the Board unless expressly so stated.

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