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Nevada State Board of Pharmacy News

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Board Appointments

Congratulations are in order for Nevada State Board of Pharmacy President Kam Gandhi's reappointment to the Board for a third term, the maximum one can serve. Kam was first appointed in November 2008, reappointed in November 2011, elected president of the Board in January 2013, and will now skillfully guide the Board through another stint. A division pharmacy manager for Albertsons, LLC, Kam is a 1995 graduate of University of Illinois College of Pharmacy, and has unselfishly served the public through his Board activities in a fair and professional manner. Board staff is delighted to support Kam for another term, and wishes him continued success.

Immunization Update

Submitted by Lillian Stoll, PharmD candidate, Chicago State University, doing a rotation at the Nevada State Board of Pharmacy

With all of the attention to the measles outbreak in our country this past year, Board staff thought it might be worth revisiting immunizations by pharmacists. Nevada remains one of the least immunized states in the nation, which led to NRS 454.213(18) regulated through the Board, authorizing pharmacists with proper training and working under a protocol to administer any vaccine to patients of any age. Consequently, Nevada pharmacists administered over 236,000 immunizations between April 2013 and March 2014, 512 of which were for measles, mumps, and rubella (MMR).

According to the Centers for Disease Control and Prevention, from January 1 to February 6, 2015, 121 people were reported to have contracted measles in the United States, including four cases confirmed in Nevada. Measles is a highly infectious airborne virus that spreads through droplets dispersed during breathing, speaking, coughing, or sneezing. These droplets remain suspended in the air for up to two hours and can easily reach and infect susceptible unimmunized individuals and, to a lesser extent, underimmunized individuals (those who have only received one dose of MMR). Ninety-nine percent of those vaccinated with MMR (0.5 mL subcutaneously; two doses separated by at least 28 days) are protected from the disease.

Who should be vaccinated? Children should receive their first dose at 12-15 months of age, followed by the second dose at four to six years of age. Post-high school adults born after 1957 who have no evidence of immunity should have at least one dose, and those attending educational institutions require two doses. Health care workers should have documented evidence of immunity.

Who should **not** be vaccinated? Immunocompromised patients and patients allergic to gelatin, neomycin, or a previous dose of MMR are candidates not to receive the vaccine.

As a reminder, pharmacists who wish to administer immunizations under the required protocol must be trained and certified to administer immunizations by completing a course approved by the Accreditation Council for Pharmacy Education and hold a current certification in life-saving techniques pursuant to American Heart Association's Basic Cardiac Life Support for Healthcare Providers or its equivalent. Those who complete an approved course may use six hours toward continuing education (CE) for the initial training and may use two hours toward CE for every recertification thereafter.

Handling of CS for Emergency Use (Ambulances and Fire Departments)

Quite often, Board staff is asked by a pharmacist how to accommodate requests for controlled substances (CS) for the stocking of ambulances, fire engines, and the like (first responders). Posing the question to the local Drug Enforcement Administration (DEA) office, the proper handling is as follows:

- The facility (ambulance company or fire department) must employ a medical director.
- The medical director registers with DEA at the address of the facility.
- The pharmacy or wholesaler sells the drugs to the facility on invoice and must utilize a DEA Form 222 presented by the facility for Schedule II CS.

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FDA's New Database Simplifies Searching for Guidance Documents

Food and Drug Administration (FDA) has released a new database that houses most FDA guidance documents for regulatory professionals. The guidance documents for nearly all FDA-regulated professions and industries are available in a searchable database that allows users to enter keywords that update automatically as they are typed. Search results may also be narrowed by product, date, document type, and other terms. The database also indicates whether there is an open comment period and the deadline for submitting comments.

The database can be accessed at *www.fda.gov/RegulatoryInformation/Guidances/default.htm*.

2014-2015 Targeted Medication Safety Best Practices for Hospitals

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 Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

The purpose of the Targeted Medication Safety Best Practices (TMSBP) for Hospitals is to identify, inspire, and mobilize widespread, national adoption of consensus-based best practices on specific medication safety issues that continue to cause fatal and harmful errors in patients despite repeated warnings in ISMP publications. These best practices are realistic practices, already adopted by many organizations, upon which hospitals can focus their medication safety efforts. The best practices are applicable to all types of hospitals including, but not limited to, critical access hospitals, cancer hospitals, and children's hospitals. They may also be applicable to other health care settings, as well as non-inpatient areas of hospitals and hospital systems. These best practices have been reviewed by an external expert advisory panel and approved by the ISMP Board of Trustees. Related issues of the *ISMP Medication Safety Alert!* are referenced after each best practice.

Recurrent Issue of Serious Harm

Oral methotrexate for non-oncological indications administered daily instead of weekly or twice weekly is a recurrent issue and one of the six TMSBPs.

ISMP has published this error in seven *ISMP Medication Safety Alert!* issues from 1996 to 2013. Although dosed daily for oncology purposes, it is used weekly or twice weekly to treat a variety of autoimmune diseases (eg, psoriasis, severe rheumatoid arthritis). Error reports point to inadvertent ordering and/or entering as daily instead of weekly or twice weekly, and lack of patient education/understanding of medication dosing schedule. To minimize the risk of error, **Best Practice 2** calls for hospitals to:

a) Use a weekly dosage regimen default for oral methotrexate. If overridden to daily, require a hard stop verification of an appropriate oncologic indication.
b) Provide patient education by a pharmacist for all weekly oral methotrexate discharge orders.

Question: Does the best practice of a weekly frequency default for oral methotrexate apply to a specialty cancer hospital?

Answer: The intent of this best practice is to reduce errors when methotrexate is prescribed as a weekly regimen for non-oncologic or oncologic indications. Even when used for oncologic purposes, oral methotrexate is sometimes prescribed as a weekly regimen, not daily. Thus, this best practice applies to all patient care settings, including specialty cancer hospitals.

Teaching Points (Both Verbal and Written)

- Explain the weekly dosing schedule.
- Explain that taking extra doses is dangerous.
- Have the patient repeat back the instructions.
- Provide the patient with the free ISMP high-alert medication consumer leaflet on methotrexate (found at *www.ismp.org/AHRQ/default.asp)*.

To read all of the best practices, visit *www.ismp.org/Tools/BestPractices/default.asp.*

ACPE Releases Updated Definition of CPE and Guidance on CPD

The Accreditation Council for Pharmacy Education (ACPE) has released two documents that provide guidance and support for continuing pharmacy education (CPE) and continuing professional development (CPD). The two documents, approved by the ACPE board of directors, are described below.

- The revised *Definition of Continuing Education for the Profession of Pharmacy* defines the quality of CPE required by ACPE and the competencies required for CPE activity content. The *Definition* document will assist providers of CPE in planning activities that will be applicable to the professional development of pharmacists and certified pharmacy technicians.
- The *Guidance on Continuing Professional Development (CPD) for the Profession of Pharmacy* incorporates feedback from a broad survey of the pharmacy profession that was conducted in July 2014. The *Guidance* document provides details on the learning activities that may contribute to the professional development of both pharmacists and pharmacy technicians beyond CPE, and also "provides a process for pharmacists and pharmacy technicians to meet and maintain defined competencies in areas relevant to their respective professional responsibilities."

Additional information, including links to the documents, is available in a press release on the ACPE website at *www.acpe-accredit.org/pdf/ACPEAdvancesCPE-CPDforPharmacists.pdf*.

Hospira Issues Recall for Multiple Lots of Ketorolac Tromethamine Injection Due to Potential Contamination

Hospira, Inc, of Lake Forest, IL, has issued a voluntary recall of ketorolac tromethamine injection, USP in the United States and Singapore due to potential particulate matter. The presence of particulate was confirmed through a customer report of visible floating particulate that was identified as calcium-ketorolac crystals. If in-

jected, medications contaminated with particulate matter may cause localized inflammation, allergic reaction, granuloma formation, or microembolic effects. Multiple lots are impacted by this recall and are listed in a press release posted to the FDA website at *www.fda.gov/Safety/Recalls/ucm433857.htm*. The lots were distributed from February 2013 to December 2014 in the US. To date, there have been no cases of adverse events associated with this medication. Adverse reactions may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program.

FDA Warns of Counterfeit Cialis Tablets Entering the US

Potentially dangerous, counterfeit versions of Cialis® 20 mg tablets were intercepted in the mail before reaching a US consumer, warns FDA. Laboratory analysis of the counterfeit product showed that it contained multiple active ingredients that could lead to adverse effects or harm if used, indicates an FDA Drug Safety Announcement. The agency reminds US consumers to only buy prescription medications from state-licensed pharmacies located in the US. FDA notes that it cannot confirm that the manufacturing, quality, storage, and handling of products ordered from unlicensed websites follow US standards because the products are from an unknown source.

To help consumers identify these counterfeit medications, FDA provides guidelines in the safety announcement. For example, these counterfeits list "AUSTR81137" on the front of the bottle and lack a National Drug Code number. Other possible identifiers include misspellings and unusual colors on the label, and a manufacturer listed as "112 Wharf Road, WEST RYDE, NSW 2114" on the side of the bottle.

To date, FDA is not aware of any adverse events associated with these counterfeit medications; however, consumers are encouraged to talk to a health care provider about their condition and options for treatment if a counterfeit product was received.

The National Association of Boards of Pharmacy® (NABP®) has reviewed more than 10,900 websites selling prescription drugs to patients in the US and found that nearly 97% are operating out of compliance with pharmacy laws and practice standards established to protect the public health. To help consumers in the US find the safest sources for purchasing medications online, NABP developed the Verified Internet Pharmacy Practice Sites® (VIPPS®) program. NABP encourages consumers to look for the VIPPS Seal and to check NABP's list of accredited sites on the AWAR$_X$E® Prescription Drug Safety Program website. In addition, consumers may soon watch for pharmacy sites using the newly launched .pharmacy Top-Level Domain; sites in the domain (with a website address ending in .pharmacy) will be reviewed by NABP and approved only if they are legitimate online pharmacies or pharmacy resources adhering to applicable pharmacy laws and best practices.

Additional details on the counterfeit Cialis are available in a Drug Safety Announcement posted to the FDA website at *www.fda.gov/Drugs/DrugSafety/ucm431071.htm*. More information on VIPPS and other NABP programs is available in the Programs section of the NABP website, *www.nabp.net*.

New FDA Drug Info Rounds Training Videos Review Drug Disposal and REMS

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. The latest Drug Info Rounds videos are as follows.

- In "Disposal of Unused Medicines," pharmacists discuss how consumers can safely dispose of expired or unused medications to prevent abuse or misuse and accidental poisoning.
- In "REMS," pharmacists discuss the many components of Risk Evaluation and Mitigation Strategies (REMS) and how they can help manage a drug product with known or potential serious risks.

Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, Division of Drug Information. These videos and previous Drug Info Rounds resources are available on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm*.

FDA Issues New Drug Labeling Rules to Benefit Pregnant, Breastfeeding Women

FDA announced new prescription drug labeling requirements that will clarify how medications might affect women who are pregnant or breastfeeding and men and women of reproductive potential. The final "Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling Rule" removes the previously used pregnancy letter categories – A, B, C, D, and X – and places information into three main categories:

- **Pregnancy:** Labor and delivery guidelines now fall under this category, which also now includes information for pregnancy exposure registries. Such registries track data on the effects of certain approved medications on pregnant and breastfeeding women.
- **Lactation:** Previously labeled "Nursing Mothers," this category provides information such as how much drug is secreted through breast milk and the potential effects on a breastfed infant.
- **Females and Males of Reproductive Potential:** This is a new category that includes information on how a certain medication might affect pregnancy testing, contraception, and infertility.

The new labeling changes go into effect on June 30, 2015. Over-the-counter medication labels will not be affected. The new rules are available for download through the *Federal Register* at *https://s3.amazonaws.com/public-inspection.federalregister.gov/2014-28241.pdf*.

FDA Approves Zohydro ER With Abuse-Deterrent Properties

In February 2015, FDA approved a new formulation of Zohydro® ER with abuse-deterrent properties. The new formulation uses a technology that allows the drug to maintain its release properties when used as intended, according to a press release from Zogenix. The abuse-deterrent system, known as BeadTek, incorporates "pharmaceutical excipients" that create a viscous gel when the medication is crushed and dissolved in a liquid or solvent, thus making the product more difficult to abuse through methods that involve crushing, breaking, or dissolving the drug. In early 2014, Zohydro ER became the first extended-release, single-ingredient hydrocodone product to receive approval for use in the US. Approval of the drug came under criticism, with some organizations arguing that the potential for addiction, abuse, and misuse could outweigh therapeutic benefits, in part because the drug lacked abuse-deterrent properties. Zogenix indicates that transition to the new abuse-deterrent formulation will take place in second quarter 2015.

Additional information on the new formulation is provided in a press release available on the Zogenix website at *http://ir.zogenix.com/phoenix.zhtml?c=220862&p=irol-newsArticle&cat=news&id=2012326*.

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- The pharmacy or wholesaler delivers the drugs to the facility (at its physical address).
- The drugs cannot be picked up by the fire chief, the medical director, or anyone else.
- The medical director (or one of his or her practitioners licensed to prescribe) orders the medication for a patient as appropriate, and that order becomes the "chart order" or "prescription" to be maintained by the facility, showing who received the dose.
- A new order is then generated by the medical director of the facility (including a DEA Form 222 if necessary) and provided to the pharmacy or wholesaler for filling and delivery to facility for replacement.
- These drugs **cannot** be dispensed by the pharmacy pursuant to a prescription (ie, "for office use" or "for ambulance use").

It Is That Time Again – Well, Almost, but Sooner Than You Think!

Nevada pharmacist licenses will expire on October 31, 2015. Once again, the on-time fee remains at $180 every two years. Renewal forms will be mailed to pharmacists approximately 45 days prior to the expiration date. It is important to notify the Board office **in writing** within 10 days of any changes to your address in order to ensure proper delivery. The Board website's Change Licensee Information page qualifies as "in writing."

As in the past, the Board will offer the option to renew **online** with a credit card. Starting mid-September, you may access the Board website's Renewal of a License page. You **must** have your renewal form in hand, as your login codes are printed specific to your license information. The Board will enclose an information sheet to troubleshoot any online login issues that may arise. It is strongly recommended to read this handy, colorful addition because it will answer any other questions a pharmacist may have during the renewal process.

The Board continues to offer the option to mail in your form and, should you choose that option, please understand that the Board office **requires a money order** as payment. The Board does not, and has not for several years, accept personal or business checks nor does it accept cash. On the chance this printed-in-red requirement is missed or any section of the form is deficient, you will significantly delay the renewal of your license since Board staff will return everything to you for correction of any and all deficiencies. The renewal form must be 100% complete in order to be considered received. When mailing in your renewal form you should allow a two- to three-week window to receive your certificate. Please remember to mail the original form. The Board does not accept copies or stamped signatures.

Part of the renewal process includes a pharmacist certifying the completion of all required CE hours. The hours are calculable at 1.25 hours per month and after the exemption period of the first two years after graduation, the total due is 30 hours every October of odd-numbered years. Please note, **all** pharmacists who live **or** practice in Nevada are **required** to complete one hour of an **approved** Nevada law CE program. This may be obtained by either attending a Board meeting (see the online schedule), attending a live program at which a Board staff member is presenting the material, **or** the Board's most popular option of using the online link from its CE web page to *Pharmacist's Letter.* The Board's website has the link to the **only** approved online program. Anything else may count toward CE; however, nothing else will count for the all too crucial Nevada law CE!

The expiration date of October 31 is to avoid late fees as you are allowed to get your renewal form postmarked up to that date without incurring late fees. If you expect to work on or after November 1, 2015, then plan in advance to either renew your license online or mail the renewal form early enough to allow for processing by staff. Should a pharmacist miss the required postmark date of October 31, 2015, then he or she should expect to include the late fee of $140, bringing the total due to renew late to $320. Of course Nevada's pharmacists would never do that!

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™ (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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