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Immunizations Expanded to Allow Meningococcal Vaccine, Intern Administration

Many in the pharmacy industry have anxiously awaited the expansion of the immunization rules to add the meningococcal vaccine to those permitted to be administered by immunizing pharmacists, and to permit properly certified interns to do immunizations under the immunizing pharmacist's personal supervision. These rules did pass the West Virginia Legislature during the 2015 Regular Legislative Session, were final-filed by the West Virginia Board of Pharmacy, and became effective May 17, 2015. So, pharmacists who hold an immunizing pharmacist permit, and properly trained and certified interns under their personal supervision, can now do immunizations for influenza; pneumococcal; hepatitis A; hepatitis B; herpes zoster; tetanus; tetanus diphtheria; tetanus, diphtheria, and pertussis; and meningococcal disease.

The schools of pharmacy in the state were the driving force for adding interns to the statute and rules to permit them to do immunizations as part of their experiential education. Generally speaking, pharmacy students are getting the required training and certification very early upon entering pharmacy school, so it makes sense that they should get to hone this skill under the eyes of a good preceptor. As such, the rules now provide that a licensed pharmacy intern may perform all of the immunizations an immunizing pharmacist can administer so long as the intern has completed all of the same training and current certification required of a pharmacist and the intern is under the personal supervision of an immunizing pharmacist. The term "personal supervision" is defined as follows: Personal supervision means the supervising immunizing pharmacist is physically present in the room during the administration of a vaccine. So, an intern who is properly trained and certified can get all of the paperwork ready and get the vaccine ready under the usual direct supervision, but the supervising immunizing pharmacist must be physically present in the same room and personally supervising the intern when the vaccine is actually administered to the patient.

While immunizing pharmacists get an immunizing pharmacist permit issued by the Board, the rules provide that interns must simply have their intern license, and then provide his or her supervising pharmacist a copy of the documentation that the intern has completed all of the training and current certification. The supervising pharmacist shall in turn maintain this documentation in the pharmacy where the pharmacist and intern who administer an immunization are employed at the time any immunization is administered by the intern.

Another nuance that changed with these rules concerns adverse events reporting. The rules have from the beginning required pharmacists to report all adverse events to the federal Vaccine Adverse Event Reporting System (VAERS) and provide a copy of the report to the Board. However, no such report has ever been provided to the Board. So, when working with the West Virginia Board of Medicine and the West Virginia Board of Osteopathic Medicine on these joint rules changes, the prescriber community voiced concern about primary care provider-level and state-level information on any adverse events. The rules were changed to add that a copy of any VAERS report must now be sent not just to the Board of Pharmacy, but also to the West Virginia Department of Health and Human Resources Bureau for Public Health, Office of Epidemiology and Prevention Services, Division of Immunization Services, and the patient's primary care physician or other licensed health care provider as identified by the person receiving the immunization.

Pharmacy Technician Trainees Must Apply With the Board Before Beginning Work

With the pharmacy technician rules changes effective May 17, 2015, pharmacies hiring new people as pharmacy technician trainees (PTTs) for in-house training have a bit of a different process to follow now. Under the old system, the pharmacy would simply fill out a PTT Notification Form and mail it to the Board within a few weeks of the PTT's start date. However, under the new scheme, these new PTTs will

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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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have to file a PTT application and submit a criminal history background check to the Board, and be granted a PTT registration prior to beginning work. They cannot begin performing any PTT functions until their application is approved by the Board and a PTT registration card is issued.

Welcome to New Inspectors and New Investigator

As many are already aware, Inspector Irvin VanMeter, RPh, has announced that he will be retiring at the end of September after 15 years of excellent service as an inspector for the Board, covering southwestern counties of the state. He will be greatly missed, and the Board very much appreciates his years of distinguished service. Over the course of Mr VanMeter's career, the number of pharmacies and other entities required to be inspected has steadily increased. As such, for several years the Board has discussed adding a fifth inspector to the roster. So, to get ready to fill the sizeable void left by Inspector VanMeter, and to handle the ever increasing workload, the Board has hired two new inspectors who are already undergoing training and are out working. They are Lisa Hedrick, RPh, from Marlinton, WV, recently employed by CVS and Rite Aid; and Don Klamut, RPh, from Wheeling, WV, recently retired from the United States Department of Veterans Affairs. Welcome to Lisa and Don!

Since there are now a total of five inspectors, territories have been realigned. The new inspectors and their territories are as follows:

- Don Klamut is covering a newly carved-out northern territory of Brooke, Doddridge, Hancock, Harrison, Marion, Marshall, Ohio, Tyler, and Wetzel counties.
- Lisa Hedrick is inspecting in a belt of counties stretching across the south-central part of the state covering Braxton, Clay, Greenbrier, Kanawha, Lincoln, Pocahontas, Wayne, and Webster counties.
- Dave Gerkin, RPh, from Parkersburg, WV, is covering a western territory of Cabell, Calhoun, Gilmer, Jackson, Lewis, Mason, Pleasants, Putnam, Ritchie, Roane, Wirt, and Wood counties.
- Roger Shallis, RPh, from Martinsburg, WV, is handling an eastern territory consisting of Barbour, Berkeley, Grant, Hampshire, Hardy, Jefferson, Mineral, Monongalia, Morgan, Pendleton, Preston, Randolph, Taylor, Tucker, and Upshur counties.
- Charles "Buck" Selby, RPh, from Cool Ridge, WV, is serving in Boone, Fayette, Logan, McDowell, Mercer, Mingo, Monroe, Nicholas, Raleigh, Summers, and Wyoming counties.

With an increase in licensees, and the ever increasing problems with drug abuse, the Board has also recognized an increase in the number of complaints and drug diversion investigations over the years. So, the Board also recently hired a new investigator for the southern half of the state, Dave Lucas, to help spread the work with current investigator, Fred Wagoner, who had been shouldering the burden alone up to this point. Like Investigator Wagoner, Mr Lucas is a 25-year veteran of the West Virginia State Police force, with vast experience working drug cases on both the state and federal levels. So, without further ado: Welcome to Dave Lucas as well!

It Is Time for Renewals

As a reminder, facility licenses and permits expire annually on June 30. Likewise, approximately half of the pharmacist and technician licenses and registrations will also expire on June 30, and are up for biennial renewal. Please note that applications not received in the office by close of business on June 30, 2015, will require payment of late fees.

The *West Virginia Board of Pharmacy News* is published by the West Virginia 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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