



Oklahoma State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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New Board Compliance Officer



The Oklahoma State Board of Pharmacy has added a new compliance officer position for a total of six compliance officers. Marty Hendrick, PharmD, DPh, of Tulsa, OK, began employment with the Board as a compliance officer on March 2, 2015. Marty graduated from the University of Oklahoma College of Pharmacy in 2006. Marty was previously employed as a pharmacy manager

for a chain pharmacy in Tulsa, and before that, worked as an independent pharmacist in Missouri. Marty will be working alongside Senior Compliance Officer Betty Beil in northeastern Oklahoma. In addition, his territory will include portions of central and north central Oklahoma. He receives email at mhendrick@pharmacy.ok.gov.

15.06. Board Revocation of Licenses

When talking with pharmacists around the state, Board members and staff are often asked about the revocation of licenses or permits. Revocation is a serious action when taken by the Board. Revocation is considered permanent and revoked licenses and permits are not eligible for reinstatement. The majority of license revocations are the result of theft, usually involving controlled substances (CS) that were stolen for illicit sale to someone else. When CS are stolen for a personal addiction, the Board usually suspends the registrant's license until the person has been in rehabilitation treatment for a sufficient time that a medical evaluation report can be issued to assure the Board that the person is able to practice safely. The Board often teams with Oklahoma Pharmacists Helping Pharmacists (OPHP) in its quest to give registrants a second chance pathway toward re-establishing themselves in a manner where they can

practice safely. In fact, the Board provides substantial support to the OPHP program each year.

The chart below provides some information on Board revocations since 2009.

Year	Technicians	Pharmacists*	Pharmacies	Wholesalers
2009	31	1		
2010	33	1		2 (Gulf Coast Pharmaceuticals, Inc; Alliance Wholesale Distributor)
2011	44	1		
2012	43	1	1 (New England Compounding Center)	
2013	47			
2014	23	2	1 (Trinity Apothecary)	

*Three of the pharmacists were convicted of felony offences and were sentenced to prison in criminal cases; one admitted guilt in selling a large quantity of Schedule V drugs; one admitted guilt in intentional overbilling third-party payers in excess of \$350,000; and one was found guilty of a substantial loss of Schedule II drugs and chose revocation rather than paying a \$4,000 fine.

15.07. OSBP-ISMP Pharmacy Practice Safety Conference 2015

In June 2015, the Board will be hosting a half-day continuing education (CE) conference aimed at

Continued on page 4



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:

- Use a weekly dosage regimen default for oral methotrexate. If overridden to daily, require a hard stop verification of an appropriate oncologic indication.
- 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 AWARE® 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>.

Continued from page 1

improving patient safety for pharmacists. Two locations are being offered this year: Oklahoma City, OK, on June 23, and Tulsa on June 24. The conference, including lunch and three hours of Accreditation Council for Pharmacy Education (ACPE)-accredited CE, is being provided without charge by the Board to further its mission of protecting the health, safety, and welfare of the citizens of Oklahoma.

Educational staff from the Institute for Safe Medication Practices (ISMP) will present three hours of ACPE-accredited CE on the topics of 1) Rooting Out Errors in Your Pharmacy and 2) There Seems to Be a Mistake With My Prescription (an ambulatory approach to responding to a medication error).

The programs will be the same for each day and no duplicate registrations are allowed. Conference details and registration information will be sent to pharmacists in early May. Information will also be posted on the Board's website under "Announcements."

15.08. Hospital Director of Pharmacy Responsibility

As the health care system in the state continues to evolve, the Board is working with health systems as they develop new business models. One of the models is a business organization model whereby physician clinics or surgery centers miles away from the main hospital are being licensed as a part of the hospital – considered essentially a remote department of the main hospital. The health department licenses them as "ABC Hospital doing business as XYZ Clinic" and lists the clinic address on the license, and also lists the number of beds for which the main hospital is licensed. In this situation, it is important for the hospital director of pharmacy to understand that it is the responsibility of the director to oversee the medication use and storage at the clinic site in the same manner as he or she would a department at the main hospital. The same review and inspection standards and detailed policies and procedures are required for these facilities just as if the clinic was "in" the main hospital. Medications transferred to these remote facilities must be recorded as required by law.

Whatever process a hospital uses to provide medications for patients, it is important that the director of pharmacy know and understand the business model being used and understand that he or she has complete responsibility for all medications whether at the main hospital or at a remote site.

Disciplinary Actions

For more information, you may view hearing minutes at www.pharmacy.ok.gov.

15.09. January 14, 2015 Board Hearing

Hali Caspers, Technician #10628 – Case No. 1302: Found guilty on three counts including possession of a

controlled dangerous substance (CDS) without a valid prescription and theft while working as a registrant. **Revoked.**

Ryan Carr, Technician #18736 – Case No. 1303: Admitted to guilt on three counts including possession of a CDS without a valid prescription and theft while working as a registrant. **Revoked.**

Jimmie Urner, DPh, #9743 – Case No. 1306: Found guilty on four counts including possession of a CDS without a valid prescription and the use or abuse of an illegal CDS substance or a positive drug screen for such illegal CDS substance or its metabolite. **Indefinite suspension.**

Impaired Pharmacist #13503 – Case No. 1307: Admitted to guilt on five counts including failing to participate in a rehabilitation program for the impaired as required by the Board. **Indefinite suspension.**

Impaired Pharmacist #13212 – Case No. 1308: Admitted to guilt on five counts including practicing pharmacy without reasonable skill and safety by reason of illness, use and/or abuse of drugs, narcotics, chemicals, or any other type of material; committing theft while practicing pharmacy; possession of a CDS without a valid prescription; and violating a voluntary or Board ordered rehabilitation program for the impaired. **Indefinite suspension.**

Dixon Farm Supply, Inc, #58-6364 – Case No. 1309: Admitted to guilt on four counts including failing to have a registered pharmacist who is in charge of the pharmacy at all times that the pharmacy is open for business; failing to ensure that only a pharmacist is responsible for control and distribution of all drugs; permitting a non-pharmacist to unlock the pharmacy area; and failing to supervise all employees as they relate to the practice of pharmacy. **One-year probation until January 14, 2016, and \$8,000 fine.**

15.10. February 25, 2015 Board Hearing

Brandi Kloeckler, Technician #17100 – Case No. 1304: Found guilty on four counts including possession of a CDS without a valid prescription; theft while working as a registrant; forging or increasing the quantity of drug in any prescription or presenting a prescription bearing forged, fictitious, or altered information; and filing a report or record that the registrant knows to be false, intentionally or negligently failing to file a report or record required by federal, state, or local laws or rules, willfully impeding or obstructing such filing, or inducing another person to do so. **Revoked.**

Diana Hayes, Technician #15801 – Case No. 1317: Admitted to guilt on four counts including possession of dangerous drugs without a valid prescription; possession of a CDS without a valid prescription; and theft while working as a registrant. **Revoked.**

Continued on page 5

Sarah Phariss, Technician #16821 – Case No. 1319:

Found guilty on three counts including theft while working as a registrant and failing to notify the Board, in writing, within 10 days of change of employment. **Revoked.**

Brent Michael Woodward, Technician #19176 – Case No. 1320:

Admitted to guilt on three counts including theft while working as a registrant and failing to notify the Board, in writing, within 10 days of change of employment. **Revoked.**

Impaired Pharmacist #14832 – Case No. 1321:

Admitted to guilt on three counts including possession of a CDS without a valid prescription and theft while practicing pharmacy. **Indefinite suspension. Pharmacist must enter into and abide by a 10-year contract with OPHP.**

Larry Vasquez, Technician #19651 – Case No. 1323:

Admitted to guilt on three counts including abusing alcohol or drugs, using an illegal CDS substance, and/or testing positive for such substance or its metabolite. **Revoked.**

Impaired Pharmacist #14268 – Case No. 1324:

Admitted to guilt on five counts including failing to procure the renewal of her license on or before the expiration date; impersonating a pharmacist; and the use or abuse of an illegal CDS substance or a positive drug screen for such illegal CDS substance or its metabolite. **License remains canceled due to failure to comply with income tax laws of the state of Oklahoma. At such time as respondent complies with the laws of the state of Oklahoma and renews her license, her license will be suspended indefinitely. Pharmacist must enter into and abide by a 10-year contract with OPHP and attend a one-day (eight-hour) law seminar during the calendar years of 2015 and 2016 in addition to the required 15 hours of CE. \$15,000 fine.**

Jessica Lopez, Technician #16597 – Case No. 1325:

Admitted to guilt on four counts including possession of a CDS without a valid prescription and theft while working as a registrant. **Revoked.**

Calendar Notes

The Board will meet on **April 22** and **June 17**. The Board will be closed Monday, **May 25**, for Memorial Day and Friday, **July 3**, for Independence Day. Future Board dates will be available at www.pharmacy.ok.gov and will be noted in the July Newsletter.

Change of Address or Employment?

Please be diligent in keeping your information up to date and if possible, remind your coworkers and employees. This continues to be an ongoing problem and failure to notify the Board is a violation of Oklahoma pharmacy law. All pharmacists, technicians, and interns must notify the Board in writing within 10 days of a change of address or employment. Online updates through the license renewal page are also accepted as official notification.

Special Notice About the Newsletter

The *Oklahoma State Board of Pharmacy Newsletter* is an official method of notification to pharmacies, pharmacists, pharmacy interns, and pharmacy technicians registered by the Board. Please read them carefully. The Board encourages you to keep them for future reference.

OPHP

If you or a pharmacist you care about is suffering from chemical dependency, there is a solution. OPHP is readily available for help. Pharmacists in Oklahoma, Texas, and Louisiana may call the OPHP help-line at 1-800/260-7574 ext. 5773. All calls are confidential.

“This publication is issued by the Oklahoma State Board of Pharmacy as authorized by Title 59 O.S. 353.7. Copies have not been printed but are available through the agency website.”

Page 5 – April 2015

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