April 2015

News

Arizona State Board of Pharmacy

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Personnel Changes at Board Office

Effective May 29 or sooner, there will be a new executive director at the Arizona State Board of Pharmacy office. The current director is retiring.

> After more than 25 years of employment with the Board, it's "time to be moving on" as the saying goes. I have enjoyed my tenure at the Board, especially the people I have met. That's what it's all about, of course: people. I have met people in a very wide spectrum, kind of like in the Clint Eastwood movie, *The Good, the Bad and the Ugly.* In the end, of course, they were all good; the situations we found them in were the good, the bad, and the ugly. I truly enjoyed meeting them all and when, like the prodigal son, someone returned to the straight and narrow from a wayward path it was truly rewarding, both for them and for me. Thanks to everyone.
>
> Hal Wand, MBA, RPh
> Executive Director

Interviews for a new director are being held soon and a new director should be in place at least 60 days before he leaves. There are two internal and two external candidates at this time.

On-Demand Inspections

Pharmacy boards around the country are being faced with nonresident pharmacies that have not been inspected in a reasonable time or in some cases have never been inspected. This of course puts the state in a position of not being sure that the pharmacy is operated in a safe or even a legal manner. As a result, many states are requiring that a recent copy of an inspection by the state of domicile accompany an initial or renewal nonresident application. This puts a hardship on the state of domicile at a time when budgets prohibit most states from performing what has come to be known as the "on-demand" inspection. Fortunately, the National Association of Boards of Pharmacy® (NABP®) has developed the Verified Pharmacy Program™ (VPP™), which can assist nonresident pharmacies in meeting the inspection requirement for some states. More information about VPP, including details on the application process, fees, and processing time, is available in the Programs section of the NABP website, *www.nabp.net.*

Fingerprints

Since the fingerprinting requirement went into effect in August 2014, the Board has processed over 3,500 sets of prints. While the process has gone fairly well, the Board has noted the following as repeat issues:

- Submission of Arizona Department of Public Safety (DPS)-issued Level One Fingerprint Clearance Cards in lieu of fingerprints. This card is not accepted.
  - **A.R.S. §32-1904(A)(6) states you must submit a set of fingerprints to the Board.**
- The Fingerprint Clearance Card can be issued even if you have a current or resolved misdemeanor/felony offense(s); however, the regulatory Board may require further information, require a Board appearance, or even deny a license.
- Failure to submit the $22 fingerprint processing fee.
  - This fee is in addition to the application fee.
  - This fee is only payable by cash, check, or money order.
  - Your prints will not be submitted for processing until the fee is paid.
- Failure to submit a completed fingerprint verification form.
  - Your fingerprint technician must complete the Board-issued fingerprint verification form, enclose the form in an envelope with your completed fingerprint card, and write his or her name across the edge of the sealed envelope.
  - You must submit the unopened envelope to the Board office with payment of the fingerprint processing fees.

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:

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*.

Continued from page 1

- Submission of damaged fingerprint cards.
  - ◊ Do not submit your fingerprint card if it has been stained, ripped, torn, or bent. DPS will reject a damaged fingerprint card, which will prolong the licensing process.
  - ◊ If you damage your fingerprint card, contact the Board office for a new fingerprint packet.
- Applicants have been contacting DPS to inquire about the status of their fingerprints.
  - ◊ DPS cannot provide information on the status of your prints.
  - ◊ The average time for processing prints is four weeks; factors such as the time it takes you to submit the card to us, missing payments, and holidays can factor into a longer processing time.

In addition, the Board has been asked by DPS to remind applicants to check with their local police or sheriff's office if they intend on getting prints done there. Not all offices provide printing services and some will only provide the service if the applicant has the fingerprint card with them.

Controlled Substances Inventory Reminder

May 1 is fast approaching and it is time for a controlled substances (CS) inventory again. Unless you have agreed on an alternative date for the annual CS inventory, May 1 is the anniversary of the signing of the Controlled Substances Act by then-President Richard Nixon. This inventory should be performed so that it is like a "snapshot" of all of the CS present in your pharmacy either at the open or close of business that day. Please contact your compliance officer if you have any questions or need to conduct the inventory either within the four days before or up to four days after the magical date.

Compounding Bill

Since the passage of the federal legislation known as the Drug Quality and Security Act, many states have passed complementary legislation. In Arizona the Board tried to as well. Sandy Sutcliffe, an attorney and Board compliance officer, wrote a great piece of legislation. Unfortunately, there was not a consensus between the various stakeholders, veterinarians, medical practitioners, and pharmacy groups to make a "package" that everyone could live with this year, so it is back to the drawing board for next year.

Disciplinary Actions and Updates

Pharmacists

Gioia, Carrie (S013712) – *Findings of Public Emergency/Order of Summary Suspension.* Suspension is in place until further notice. Effective January 28, 2015.

Ornelas, David (S009841) – One-month suspension (February 1, 2015 – March 1, 2015), followed by five-year probation, Pharmacists Assisting Pharmacists of Arizona contract, 400 hours community service. Effective January 28, 2015.

Pharmacy Technicians

Bailey, Carmen (T043497) – Application initially denied. Board instructed applicant to reapply. Applicant may request appearance in front of Board to continue licensure process. Effective January 28, 2015.

Downing, Kelly (T007378) – License revoked. Effective January 28, 2015.

Graves, Amber (T028457) – License revoked. Effective January 28, 2015.

Hays, Stacey (T027333) – License revoked. Effective January 28, 2015.

Smith, Iyonna (T043898) – Application initially denied. Applicant may request appearance in front of Board to continue licensure process. Effective January 28, 2015.

Stout, Jessica Rebecca (T026766) – License revoked. Effective January 28, 2015.

White, Aaron (T041931) – Application initially denied. Applicant may request appearance in front of Board to continue licensure process. Effective January 28, 2015.

Disciplinary Actions and Updates – Other Health Profession Boards

Arizona Medical Board

Waqas Ali, MD #47449 – *Order for Surrender of License and Consent to the Same.* Respondent ordered to surrender his license for the practice of allopathic medicine in the state of Arizona immediately. Effective December 3, 2014.

Aimee L. Butel, MD #35660 – *Order for Suspension and Consent to the Same.* Respondent's license is suspended indefinitely beginning on the effective date of this order. Respondent may request release from suspension from the Board in writing. Reinstatement shall not be granted until after respondent completes a clinical competency assessment at a facility approved by the Board or its staff, and provides the Board with the assessment report for the Board's consideration. The Board retains sole discretion to determine whether additional restrictions, terms, or conditions should be set on respondent's reinstatement. Effective December 3, 2014.

Lawrence Cronin, MD #18696 – *Interim Consent Agreement for Practice Restriction.* Respondent is prohibited from engaging in the practice of medicine in the state of Arizona until he applies to the Board and receives permission to do so. Effective December 22, 2014.

Paul A. Guzman, MD #33313 – *Order for Surrender of License and Consent to the Same.* Respondent ordered to surrender his license for the practice of allopathic medicine in the state of Arizona immediately. Effective December 3, 2014.

Continued on page 5

Continued from page 4

George F. Gwinn, MD #25811 – *Interim Findings of Fact, Conclusions of Law and Order for Summary Suspension of License.* Respondent's license to practice allopathic medicine in the state of Arizona is summarily suspended. Respondent is prohibited from practicing medicine in the state of Arizona and from prescribing any form of treatment including prescription medications or injections of any kind. Effective December 19, 2014.

Georg Hernandez, MD #13413 – *Order for Surrender of License and Consent to the Same (Non-Disciplinary).* Respondent ordered to surrender his license for the practice of allopathic medicine in the state of Arizona immediately. Effective December 3, 2014.

Min Ying Lim, MD #40179 – *Interim Consent Agreement for Practice Restriction.* Respondent is prohibited from engaging in the practice of medicine in the state of Arizona until she applies to the executive director and receives permission to do so. Respondent may not request release from or modification of this interim consent agreement until she has completed a comprehensive chemical dependency evaluation and any recommendations that arise as a result of the evaluation, including additional treatment. Effective December 4, 2014.

Robert W. Sommer, MD #31443 – *Interim Findings of Fact, Conclusions of Law and Order for Summary Suspension of License.* Respondent's license to practice allopathic medicine in the state of Arizona is summarily suspended. Respondent is prohibited from practicing medicine in the state of Arizona and from prescribing any form of treatment including prescription medications or injections of any kind until receiving permission from the Board to do so. Effective February 2, 2015.

Peter Tsai, MD #45470 – *Order for Surrender of License and Consent to the Same.* Respondent ordered to surrender his license for the practice of allopathic medicine in the state of Arizona immediately. Effective December 3, 2014.

Timothy Walker, MD #11843 – *Interim Order for Practice Limitation and Consent to the Same (Non-Disciplinary).* Physician's practice is limited in that he shall not practice medicine in the state of Arizona and is prohibited from prescribing any form of treatment including prescription medications until the physician applies to the Board and receives permission to do so. Effective December 24, 2014.

The *Arizona State Board of Pharmacy News* is published by the Arizona 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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