April 2012

News

Arizona State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

1616 W Adams St, Suite 120 • Phoenix, AZ 85007 • Web site: *www.azpharmacy.gov*
E-mail: chunter@azpharmacy.gov

Board of Pharmacy Offices Move Again

The Arizona State Board of Pharmacy has been given the opportunity to once again demonstrate that we are "team players." The Board has been asked by the governor's office staff to pack everything up and move again. The good news is that the Board has been assured that all of the expenses associated with the move will be covered by the state this time. The office has moved to the State Land Department building located at 1616 W Adams Street, Suite 120. It is across from Wesley Bolin Park, which is only about two blocks northeast of the Board's current location. **The mailing address is PO Box 18520, Phoenix, AZ 85005-8520. Please do not mail anything to the street address; the Postal Service will not deliver mail to that address.** UPS and FedEx will still deliver to the street address. The offices are on the western part of the first floor. The Board meeting room will be a little bigger and hopefully more efficient because it is almost square. Most offices will be a little smaller, windowless, and less efficient though. Parking is limited and may become an issue; preliminary plans are that a large multistory gated garage north and east of the building will be left open on Board meeting days. By working together we can guarantee that the move will be a positive one. It will be interesting to see how long the Board continues to get mail addressed to the executive tower since the Board still gets mail addressed to the old Glendale location, which the Board left about five years ago. Special thanks to Scott Smith, who is the governor's deputy chief of staff as well as acting director of the Arizona Department of Administration for his efforts to make sure the move was "painless" and as inexpensive as possible.

New Board Compliance Officer

Steven J. Haiber, a pharmacist who just completed a year as Board president as part of his five-year term on the Board of Pharmacy, has been selected to be the Board's 5th compliance officer. Steve is a graduate of the University of Maryland as is Deputy Director Cheryl Frush ("GO TERPS"). He has a wide variety of pharmacy experience and is well known as a "problem solver" and "techie" (gadget guru) who has served on the Task Force on Internet Pharmacy Practice at the National Association of Boards of Pharmacy® in Mount Prospect, IL. Please welcome Steve and help him get through his territory his first year. Cheryl and the other four compliance officers will guide and inspire him during the "learning curve" for the position, which can last up to 18 months.

Pharmacy Self-Inspection Pilot Program

Rich Cieslinski, one of the Board compliance officers, will be sending each pharmacy in his territory at least one and maybe several new self-inspection forms. If you receive a copy of the self-inspection documents, please follow the instructions and complete them as soon as practicable. Remember, the primary objective of these self-inspections is to assist you and your staff and to provide an opportunity to identify and correct possible areas of noncompliance with state and federal law. The self-inspection should serve as an educational tool to help you better prepare for the follow-up compliance officer's inspection. If you have all the necessary documentation available from your completed self-inspection forms it will not only make the routine pharmacy inspection a good learning experience, but you may be surprised that it goes quicker than it did in the past. This self-inspection process is intended to minimize the time the compliance officer is in the pharmacy and to make it a less stressful experience for all parties involved in the process.

Long-Term Care Task Force – Five-Year Rules Revision

The Board of Pharmacy is required to review all of its rules at least every five years or the rules may be deleted. I have always wanted to see if that might not be such a bad thing; a completely fresh start would be nice, but unfortunately chaos would probably reign without rules. The governor's office recently removed the moratorium on new rules, which had been

Continued on page 4

DEA Provides Information Regarding Carisoprodol Prescriptions

A Drug Enforcement Administration (DEA) announcement provides information regarding the scheduling of carisoprodol, effective as of January 11, 2012. The DEA Final Rule making the drug a Schedule IV controlled substance was published December 12, 2011, and states that effective January 11, 2012, all prescriptions for drugs containing carisoprodol shall comply with DEA regulations. Specifically, a pharmacy may only fill or refill a prescription for a drug containing carisoprodol if all of the following requirements are met:

- the prescription was issued for a legitimate medical purpose by a DEA-registered practitioner acting in the usual course of professional practice (21 CFR §1306.04);
- the prescription contains all the information required by 21 CFR §1306.05; and
- the number of refills authorized by the prescribing practitioner is five or less (21 USC §829(b)).

The full text of the notice is available on the DEA Web site at *www.deadiversion.usdoj.gov/drugs_concern/carisoprodol/index.html.*

Pfizer Recalls Several Lots of Two Oral Contraceptive Products

Pfizer Inc recalled 14 lots of Lo/Ovral®-28 (norgestrel and ethinyl estradiol) tablets and 14 lots of norgestrel and ethinyl estradiol tablets (generic) due to potential for inexact count and out-of-sequence tablets. A Pfizer investigation found that some blister packs of the affected products may contain an inexact count of inert or active ingredient tablets and that the tablets may be out of sequence. As a result of this packaging error, the daily regimen for these oral contraceptives may be incorrect and could leave women without adequate contraception, and at risk for unintended pregnancy. Food and Drug Administration (FDA) advises that patients who have the affected product should notify their physician and return the product to the pharmacy. A Pfizer press release includes a list of the affected products with the National Drug Code (NDC) number, lot number, and expiration date for each, and is available at *www.fda.gov/Safety/Recalls/ucm289770.htm.*

Changes in Medication Appearance Should Prompt Investigation by Pharmacists and Patients

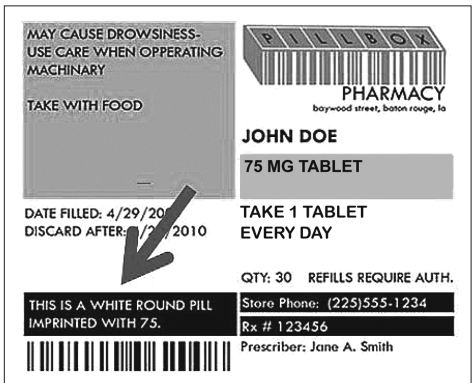
This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies 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 is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also an FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at* www.ismp.org. *ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

As the numbers of generic products continue to increase, it seems that both patients and practitioners have become desensitized to changes in medication appearance. So much so that patients may not question a change or, when they do, practitioners may simply reassure them that it was due to a change in manufacturer without actively investigating the reason. It is not uncommon for ISMP to receive reports from both practitioners and consumers where a change in medication appearance was not fully investigated and subsequently contributed to an error.

In one case, a man shared an account of what his 86-year-old father experienced over the course of nine days after his prescription for minoxidil was mistakenly refilled with another medication. He had been taking minoxidil 2.5 mg for years at a dose of 5 mg (2 tablets) twice daily. Due to failing vision, he did not realize that his minoxidil tablets looked different. His daughter noticed the change, but was unconcerned since the tablets had previously changed appearance. The pharmacy was contacted about the change and a staff member explained that it was a different generic for minoxidil, and that the pills could be exchanged for those that he usually received. There was no mention of a mistake being made when the medication was exchanged. He was taken to the hospital the following day, when he could barely walk.

After this incident was explained to hospital staff, they contacted the pharmacy. It was then revealed that he was given methotrexate by mistake because the bottles were stored next to each other. By this time, the man had taken 36 methotrexate 2.5 mg tablets, his white blood cell and platelet counts were extremely low, and he was in critical condition. We later learned that he passed away during that hospital visit.

Your pharmacy may be providing an important patient safety tool on the prescription label that may be overlooked by patients and their caregivers: a description of the shape, color, and imprint code of the medication that should be inside. This information can help ensure accuracy since it's based on the NDC number. Teach patients to look for this description and question any differences. In addition, the patient needs to know if the medication name on the pharmacy generated label is the medication he or she was expecting to receive. Even if the generic manufacturer is different each time the prescription is renewed, the description on the label should match the NDC number and thus the product inside.



With so much information on prescription labels such as patient and doctor name, drug name, instructions, and warnings – this added information can easily be missed. But it's important, so look for it and put it to use!

FDA Reminder: Purchasing Unapproved Injectable Cancer Medications Threatens Patient Safety

FDA is reminding health care providers to obtain and use only FDA-approved injectable cancer medications purchased directly from the manufacturer or from wholesale distributors licensed in the United States. FDA explains that "current shortages of injectable cancer medications may present an opportunity for unscrupulous individuals to introduce non-FDA approved products into the drug supply, which could result in

serious harm to patients." FDA reports that the agency is aware of promotions and sales of unapproved injectable cancer medications directly to clinics in the US and that the medications were likely administered to patients. Examples of products include unapproved versions of FDA-approved medications such as Faslodex® (fulvestrant), Neupogen® (filgrastim), Rituxan® (rituximab), and Herceptin® (trastuzumab). FDA stresses the risks to patients when such unapproved medications are used. The agency outlines several steps health care providers should take to ensure patient safety:

1. Obtain and use only FDA-approved injectable cancer medications purchased directly from the manufacturer or from wholesale distributors licensed in the US. An FDA Web page, *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm,* provides the online resource for each state for verifying that a wholesale distributor is appropriately licensed.
2. Determine if the medication you have received is FDA-approved by checking the Orange Book or searching the Drugs@FDA database.
3. Question whether a price sounds too good to be true. Deep discounts may be offered because the product is stolen, counterfeit, or unapproved.
4. Carefully inspect the product and packaging and be alert for signs that the product is not FDA approved, such as if the packaging looks different or the dosing recommendations are unfamiliar.

FDA also notes that if a health care provider receives multiple complaints about the same product, such as a new side effect or lack of therapeutic effect, these may signal a product quality issue.

FDA reminds health care providers that in certain circumstances the agency may authorize limited importation of medications that are in short supply. Such medications are imported from approved international sources and distributed in the US through a controlled network, and would not be sold in direct-to-clinic solicitations. If FDA has arranged for limited importation of the foreign version of a medication, information on obtaining that medication will be available in the Drug Shortages section of the FDA Web site, *www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm.*

Additional details are provided in an FDA Drug Safety Communication, available at *www.fda.gov/downloads/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/UCM287717.pdf.*

Insulin Pens Should Not Be Used for Multiple Patients, Stresses CDC

Centers for Disease Control and Prevention (CDC) issued a notice, reminding health care providers that insulin pens are intended for use by a single patient, and should never be used on more than one patient. CDC indicates that the agency has become "increasingly aware of reports of improper use of insulin pens, which places individuals at risk of infection with pathogens including hepatitis viruses and human immunodeficiency virus (HIV)." The notice explains that regurgitation of blood into the insulin cartridge can occur after injection, creating a risk of bloodborne pathogen transmission if the pen is used for more than one person, even when the needle is changed. CDC provides the following recommendations to help protect patient safety:

- Insulin pens containing multiple doses of insulin are meant for use on a single person only, and should never be used for more than one person, even when the needle is changed.
- Insulin pens should be clearly labeled with the person's name or other identifying information to ensure that the correct pen is used only on the correct individual.
- Hospitals and other facilities should review their policies and educate their staff regarding safe use of insulin pens and similar devices.
- If reuse is identified, exposed persons should be promptly notified and offered appropriate follow-up including bloodborne pathogen testing.

The notice may be downloaded from the CDC Web site at *www.cdc.gov/injectionsafety/PDF/Clinical-Reminder-insulin-pen.pdf.*

US Public Health Service Report Supports Maximizing the Scope of the Pharmacist as Part of Health Care Team

Presenting an evidence-based discussion of the comprehensive patient care services that pharmacists currently provide, a new government report calls for expanded support for such pharmacist-delivered patient care models. The report, *Improving Patient and Health System Outcomes through Advanced Pharmacy Practice,* prepared by the Office of the Chief Pharmacist, US Public Health Service (PHS), is organized into four focus points as follows:

- Focus point 1 discusses how pharmacists are integrated in many practice settings as health care providers, such as through collaborative practice agreements, and provides data showing interprofessional support for such models.
- Focus points 2 and 3 support recognition of pharmacists as health care providers and compensation models that will allow pharmacists to continue to improve patient and health care system outcomes.
- Focus point 4 presents a review of numerous peer-reviewed studies that demonstrate favorable outcomes from pharmacist-delivered care.

RADM Scott Giberson, chief professional officer, PHS Pharmacists, and the primary author of the report, stated that "one of the most evidence-based and cost-effective decisions we can make as a nation is to maximize the expertise and scope of pharmacists, and minimize expansion barriers to successful health care delivery models." The report may be downloaded from the US PHS Web site at *www.usphs.gov/corpslinks/pharmacy/comms/pdf/2011AdvancedPharmacyPracticeReporttotheUSSG.pdf.*

Continued from page 1

in place for about three years, so there is an immediate need to start working on a backload of rules requiring review. A task force on long-term care facility pharmacy rules will soon be appointed by Mr Dan Milovich, Board of Pharmacy president. The task force will be headed By Dr Jim Foy who was appointed chairman of the task force by president Milovich at the March 15 Board meeting. Any interested pharmacists should submit their résumés and a cover letter describing why they should be selected to serve on the task force to Cindy Hunter, executive secretary to the executive director of the Board, at PO Box 18520, Phoenix, AZ 85005-8520. The rules being reviewed will be Arizona Administrative Code R4-233-701, R4-23-701.01, R4-23-701.02, R4-23-701.03, and R4-23-703, which can be reviewed at the hyperlink *http://azsos.gov/public_services/Title_04/4-23.htm#Article_7*.

It is anticipated that at least three task force meeting sessions will need to be held before a draft presentation is made to the Board.

Disciplinary Actions

Notice: Before making a prescription-dispensing or other decision pursuant to information in this issue, you are encouraged to verify the current condition of a license with the appropriate licensing agency (Board).

Pharmacists

Coppola, Thomas (S017161) – $500 fine within 90 days and eight continuing education (CE) hours within 180 days. Effective January 25, 2012.

Nicolais, John (S008066) – $500 fine within 90 days and three CE hours within 180 days. Effective January 25, 2012.

Tejani, Dianne (S014682) – $1,000 fine and six CE hours within 90 days. Effective January 25, 2012.

White, Abigail (S016280) – Five years probation, Pharmacists Assisting Pharmacists of Arizona contract, cannot be preceptor or pharmacist-in-charge while on probation. Effective January 26, 2012.

Pharmacy Technicians

Kirby, Brenda (No No. Issued) – Application for licensure as a pharmacy technician trainee denied. Effective January 25, 2012.

Disciplinary Updates and Actions – Other Boards

Arizona Medical Board (MDs)

Arcotta, Karen F. (MD 15646) – License surrendered to the Arizona Medical Board. Effective February 3, 2012.

Chirban, Angelo L. (MD 27055) – License revoked. Effective January 18, 2012.

Jasin, Walter J. (MD 10086) – Non-Disciplinary – Consent Agreement for Practice Limitation – 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 physician applies to the Arizona Medical Board and receives permission to do so. Effective December 12, 2011.

Jessop, Darrell J. (MD 23441) – Letter of Reprimand, Probation, and Practice Restriction – Letter of reprimand issued. Respondent placed on five-year probation with set terms and conditions. Respondent placed on a practice restriction under which he is restricted from prescribing any controlled substance for a period of five years. Effective March 12, 2012.

Liang, Peter Chi-Yue (MD 34107) – License inactive with cause. Effective March 7, 2012.

O'Connor, Arthur J. (MD 6361) – License revoked. Effective January 19, 2012. Motion for rehearing filed January 18, 2012. Motion for rehearing denied February 1, 2012.

Ogbonnaya, Gabriel U. (MD 32142) – License revoked. Effective March 9, 2012, if no petition for rehearing or review is filed. Petition for rehearing filed. Outcome pending April 4, 2012 Board meeting.

Sara, George S. (MD 15912) – Consent Agreement for Practice Restriction – For a period of 15 years, respondent's practice is restricted as follows: respondent shall not practice interventional or pharmacologic pain management; respondent may perform the following procedures for operative patients only: administration of general anesthesia, interscalene injections for shoulder surgeries, femoral nerve injections for anterior cruciate ligament or total knee surgeries, peribulbar injections for ocular cataract surgeries, axillary brachial plexus injections for arm surgeries, lumbar subarachnoid injections for lower body surgeries where a contraindication for general anesthesia exists, or ankle blocks or field injections for foot surgeries. Effective December 14, 2011.

Smith, Sandra M. (MD 8425) – Non-Disciplinary – Consent Agreement for Practice Limitation – Physician's practice is limited in that she shall not practice medicine in the state of Arizona and is prohibited from prescribing any form of treatment including prescription medications until physician applies to the Arizona Medical Board and receives permission to do so. Effective December 9, 2011.

Swanson, Jay (MD 27669) – License inactive with cause. Effective February 7, 2012.

Arizona Board of Podiatry Examiners (DPMs)

Shapiro, Elaine J. (DPM 0174) – Findings of Public Emergency – License held by respondent summarily suspended pending proceedings for revocation and other action by the Board. Effective December 30, 2011.

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, Inc, to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

Hal Wand, MBA, RPh - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Larissa Doucette - Communications Manager