New Board Compliance Officer

Chelsea Church, DPh, PharmD, BCPS, of Tuttle, OK, began employment with the Oklahoma State Board of Pharmacy as a compliance officer on February 29, 2012. Chelsea graduated from the University of Oklahoma College of Pharmacy in 1998 and completed a primary care pharmacy practice residency in Tuscaloosa, AL, in 1999. Chelsea was previously employed as an associate professor of pharmacy practice for Southwestern Oklahoma State University College of Pharmacy. Chelsea’s territory includes south central and south western Oklahoma. She receives e-mail at cchurch@pharmacy.ok.gov.

12.05. New Technician Application Includes Exam

Beginning April 1, 2012, the application for a new pharmacy technician will include an exam containing law and conversion questions. This exam is to be used as a training tool. A pharmacist shall administer this exam as a prerequisite for approving an Oklahoma State Board of Pharmacy technician application. The pharmacist shall correct the exam, review incorrect answers with the technician applicant, and keep the original exam in the technician’s training file for review by Board staff during inspections. The pharmacy policy and procedure training manual should reference this examination. The Board will rely on the pharmacy to determine a successful exam score. The exam may be administered as an open book exam if desired by the pharmacist conducting the technician training. Answers are not provided for the exam as pharmacists should know the answers, but the law book reference that provides the answer is noted by each question. Please destroy all previous copies of the pharmacy technician application and use the new technician application available at www.pharmacy.ok.gov.

12.06. Due Diligence

Drug Enforcement Administration (DEA), Oklahoma Bureau of Narcotics (OBN), and the Board of Pharmacy all hold pharmacists responsible for the prescriptions they fill, and pharmacists must not “blindly” fill prescriptions without question. Pharmacists have a legal corresponding responsibility to determine that prescriptions have been issued for a legitimate medical purpose and there is a valid patient-practitioner relationship.

Keep in mind that pharmacies are not judged purely by volume. There are many possible reasons for a pharmacy to fill a high volume of controlled dangerous substances (CDS) and other prescriptions, which may include location, pricing, and service. However, there are steps that pharmacists should take to exercise due diligence when filling controlled substances.

Are You?
♦ Checking the prescription monitoring program (PMP)
♦ Documenting early refills and lost or stolen medications
♦ Verifying unfamiliar physician licenses/DEA numbers
♦ Calling back when unfamiliar physicians call in a prescription
♦ Using the Internet or phone book for the physician’s telephone number – forgers often use their own phone number on a forged blank

Do You?
♦ Have many patients coming in from long distances
♦ Have multiple patients at the same address, especially getting the same medications
♦ Have multiple patients arriving in the same car
♦ Have the same person picking up prescriptions for multiple persons
♦ Have an abnormally high percentage of cash prescriptions vs. insurance

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.deadversion.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 norgestimate 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/FALL-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 any 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 expected 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.

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.


**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.

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Pharmacists & Technicians: Don't Miss Out on Valuable CPE Credit. Set Up Your NABP e-Profile Today!

CPE Monitor™ integration is underway. Soon all Accreditation Council for Pharmacy Education (ACPE)-accredited providers will require you to submit your NABP e-Profile ID, assigned when you set up your NABP e-Profile, along with your date of birth (MMDD), in order to obtain continuing pharmacy education (CPE) credit for any ACPE-accredited activity. Many have already begun to do so.

Visit www.MyCPEmonitor.net to set up your e-Profile and avoid possible delays in your CPE reporting.

CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their completed CPE credit electronically.
Have patients mailing prescriptions to your pharmacy from outside your customer area or even out of state. Avoid “cookie cutter” prescriptions as doses should be individualized. Keep in mind that the maximum daily dose for acetaminophen has been lowered to 3,000 mg/day and this may affect the frequency or dose of a prescription. Ask yourself if the physician can realistically see that many patients in a day.

Board regulations and rules require that all pharmacies have a written policy and procedure manual addressing the different components of their practice, and specifically policies and procedures regarding drug diversion prevention and detection.

From the Inspector’s Desk

♦ 12.07. USP 795/797: Compounding pharmacies are now expected to be in full compliance with United States Pharmacopeia (USP) Guidelines 795 (nonsterile products) and 797 (sterile products). These rules may be found in Section OAC 535:15-10 of the Oklahoma Pharmacy Lawbook. Compounding pharmacists should be familiar with these regulations and act accordingly. Hazardous chemicals (which may include hormones) must be prepared in a Class I biological safety cabinet.

♦ 12.08. Fioricet is to be Reported to the PMP: The Uniform Controlled Dangerous Substances Act as set forth in 63 O.S. §2-208(A)(1) provides that any substance containing any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid is a Schedule III controlled substance. A recent opinion of the US District Court clarified the status of Fioricet® (generics) as a controlled drug. Based upon this ruling and the subsequent Oklahoma State Board of Pharmacy interpretation of OAC 535:1-14-4, the OBN will require all dispensers to report Fioricet as a Schedule III controlled substance to the PMP. Fioricet (generics) should be treated as a controlled drug and included on your controlled drug inventory.

♦ 12.09. Telephoned Prescriptions: Pharmacists must take new telephoned prescriptions from a physician’s office. Technicians are prohibited by law from receiving telephoned prescriptions. [OAC 535:15-5-7.5.]

♦ 12.10. Transferred Prescriptions: Prescription transfers must be between two pharmacists or interns. Technicians are prohibited from taking prescription transfers. [OAC 535:15-3-12.]

♦ 12.11. New Telephoned Prescriptions: A new telephoned prescription must be entered into the computer system as a new prescription. If the pharmacy scans new prescriptions, then the new telephoned prescription must be scanned and entered as a new prescription. Retrieving a patient’s old prescription information from the computer and creating a new one from that data, even if it is by the same pharmacist and for the same medication and directions, is not permissible. The new telephoned prescription that is reduced to writing will have the receiving pharmacist’s identification and thus must be filed for documentation of responsibility.

Disciplinary Actions

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


Machelle Abbe, Tech #6792 – Case 1079: Admitted to theft, possession of a CDS without a prescription. Revoked. (Agreed Order.)

Kaylea Ammann, Tech #9210 – Case 1080: Admitted to theft, possession of a CDS without a prescription. Revoked. (Agreed Order.)

Shelly Berryhill, Tech #6611 – Case 1081: Found guilty of theft, unlawful distribution of CDS. Revoked.


April Lopez, Tech #9686 – Case 1083: Admitted to theft, possession of a CDS without a prescription. Revoked. (Agreed Order.)

Nelson Lee, Tech #8758 – Case 1084: Admitted to conviction of a felony. Revoked. (Agreed Order.)

Travis Brawley, Tech #8779 – Case 1085: Found guilty of providing false information on technician renewal regarding charges and convictions. Revoked.

Amanda Romine, Tech #4338 – Case 1086: Found guilty of receiving, filling, and delivering a prescription without the direct supervision of a licensed pharmacist. Suspension and $2,000 fine. Permit will be placed on probation upon payment of fine. Must attend an eight (8)-hour law seminar by January 18, 2013.

Roberts Drugs Store, #24-5489 – Case 1087: Admitted to failure to guard against drug diversion. Two (2) years probation until January 18, 2014, and $10,000 fine. Pharmacy must develop and institute policies and procedures for CDS diversion, lock up all Schedule II drugs and hydrocodone. (Agreed Order.)

April Lopez, Tech #9686 – Case 1083: Found guilty of theft, possession of a CDS without a prescription. Revoked. (Agreed Order.)

James Kelley, DPh, #9468 – Case 1089: Admitted to failure to guard against drug diversion. Two (2) years probation until January 18, 2014, and $5,000 fine. Pharmacy must develop and institute policies and procedures for CDS diversion, lock up all Schedule II drugs and hydrocodone. (Agreed Order.)

J. Mark Holley, Tech #142 – Case 1090: Admitted to failure to guard against drug diversion. Two (2) years probation until January 18, 2014, and $5,000 fine. Must attend an eight (8)-hour law seminar in 2012. (Agreed Order.)

Apollo Service, #88-S-2203 and Apollo Medical Services, #2-S-2834 – Case 1092: Admitted to conducting business without a valid license. $1,000 fine each. (Agreed Order.)

Continued on page 5
12.13. March 7, 2012 Board Hearing

Gayle “Gus” Guthrie, DPh, #7265 – Case 1088: Found guilty of failure to guard against drug diversion. **Indefinite suspension and $4,000 fine.**

Tyron W. Beck, Tech #14216 – Case 1093: Admitted to theft, possession of a CDS without a prescription. **Revoked.** (Agreed Order.)

Irum Khan, Tech #13359 – Case 1095: Admitted to theft, possession of a CDS without a prescription. **Revoked.** (Agreed Order.)

Zebakiah Leon Nemecek, Tech #14759 – Case 1096: Found guilty of theft, unlawful distribution of CDS. **Revoked.**

Darren Oulliber, Tech #11646 – Case 1097: Admitted to theft of money. **Revoked.** (Agreed Order.)

Lisa Sawyers, Tech #2787 – Case 1098: Found guilty of theft of money. **Revoked.** (Agreed Order.)

Stephanie Semrad, Tech #11621 – Case 1099: Admitted to positive drug screen for Schedule I drug. **Revoked.** (Agreed Order.)

Jose Viezcas, Tech #12933 – Case 1100: Admitted to theft, possession of a CDS without a prescription. **Revoked.** (Agreed Order.)

Charlie Yang, Tech #14854 – Case 1101: Admitted to theft of merchandise. **Revoked.** (Agreed Order.)

Impaired Pharmacist #10336 – Case 1102: Found guilty of violation of Oklahoma Pharmacists Helping Pharmacists (OPHP) contract. **Indefinite suspension. Must enter and abide by a lifetime contract with OPHP.**

Jim Hall, DPh, #8642 – Case 1103: Found guilty of possession of CDS without a prescription, filling a prescription without authorization. **Indefinite suspension and $5,000 fine.**

Impaired Intern #7452 – Case 1104: Found guilty of violation of OPHP contract. **Must enter and abide by a 10-year contract with OPHP. Must not have access to CDS during remaining rotations.**

Warren Meador, DPh, #8680 – Case 1105: Admitted to filling 57 prescriptions without authorization. **$6,000 fine. 2012 CE requirements must include 15 hours of live CE plus an eight (8)-hour law seminar. 2013 CE requirements must include 15 hours of live CE.** (Agreed Order.)

Impaired Pharmacist #13224 – Case 1106: Found guilty of theft, violation of OPHP contract. **Indefinite suspension and $2,500 fine.**

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**Calendar Notes**

The Board will meet on **April 26** and **June 20**. The Board will be closed Monday, **May 28**, for Memorial Day and Wednesday, **July 4**, for Independence Day. Future Board dates will be available at [www.pharmacy.ok.gov](http://www.pharmacy.ok.gov) and will be noted in the July Newsletter.

**Change of Address or Employment?**

All pharmacists, technicians, and interns must notify the Board in writing within 10 days of a change of address or change of 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.

**Oklahoma Pharmacists Helping Pharmacists**

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.

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