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News

SC Department of Labor, Licensing, & Regulation – Board of Pharmacy

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Senate Confirms Pisarik to Lead LLR

Holly Gillespie Pisarik, JD, is the new director of the South Carolina Department of Labor, Licensing, and Regulation (LLR). She was appointed by Governor Nikki R. Haley on March 2, 2012, and confirmed by the Senate on March 29, 2012.

At the time of her appointment, Pisarik was serving as LLR's chief advice counsel. At LLR, Pisarik advised professional and occupational licensing boards on statutory and regulatory matters, provided legal advice to staff, drafted legislation for the boards and other agency programs, and managed a team of attorneys.

Before coming to LLR, Pisarik worked at Nelson Mullins Riley & Scarborough, LLP, practicing primarily in the area of health care, and representing clients before federal, state, and administrative law courts and administrative agencies.

Prior to law school, Pisarik worked for the Florida Department of Health as a public information officer and program manager.

Pisarik graduated from the University of South Carolina School of Law in May 2007, where she earned the Bronze Compleat Lawyer Award. She earned her undergraduate degree in business administration, with an emphasis on health care administration, from Winthrop University in Rock Hill, SC, in 1999.

Pisarik is a member of the South Carolina Bar, the South Carolina Women Lawyers Association, the American Bar Association, and Trenholm Road United Methodist Church in Columbia, SC. She is married and has two children.

Pharmacy Technician Renewals

The 2012 renewal notices were mailed to pharmacy technicians on or about April 15. You will be mailed a renewal notice with a **user ID** and a **password** to allow you to access the online renewal Web site. **If you are a state-certified pharmacy technician, you must mail a copy of your current national certificate (from the Pharmacy Technician Certification Board) to the South Carolina LLR – Board of Pharmacy.**

If you choose not to renew online, you may download the renewal application and renew by mailing the completed form and proper fees to the Board office. **Applications need to be received in the Board office by June 1, 2012. Pharmacy technicians who do not renew prior to June 30, 2012, will be assessed penalties and cannot work as pharmacy technicians until a 2012-2013 registration is in hand or disciplinary action may result.** If you do not renew online, please document the date the application is mailed. **The Board of Pharmacy recommends the paper renewal be sent via certified mail with a return receipt requested.**

Continuing Education Reporting for Pharmacy Technicians

In order to renew online, you must indicate that you have completed the required 10 hours of continuing education (CE) (four hours must be live). **You cannot renew until you have completed the CE requirements.** After renewals are processed, a random CE audit will be conducted. If you are selected for the audit, please respond promptly. Disciplinary action will be taken if you cannot show that you completed the CE requirements or if the required CE is dated after your renewal is received in the Board office.

Facility Permit Renewals

The permit renewal notices and forms were mailed out in mid-April 2012 to the last known address on file in the Board office. If you are a permit holder and have not received your permit renewal application, contact the South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy office immediately. The renewal notice you receive will contain a **user ID** and **password** to allow you access to the online renewal Web site.

If you choose not to renew your permit online, you may download a renewal form from the Board's Web site. Mail the completed form, along with proper fees, to the Board at PO Box 11927, Columbia, SC 29211. All applications must be received at the Board's office prior to June 1, 2012, or a $50 late fee will be assessed. After June 30, 2012, the facility permit will lapse.

Upon application for reinstatement, the facility will be assessed a penalty of $10 a day until the permit is reinstated, plus the $50 late fee and a new application fee. Depending upon the circumstances, the facility, the pharmacist-in-charge, and/or the pharmacists who practice in the pharmacy may be charged with violations of the South Carolina Pharmacy Practice Act for operating without a permit pursuant to §40-43-83 resulting in discipline.

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

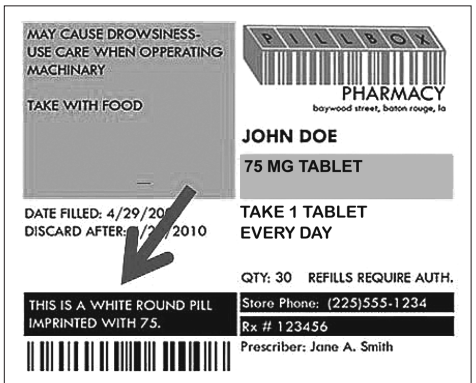
This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies 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.*

New Director Named for DHEC – Bureau of Drug Control

The South Carolina Department of Health and Environmental Control (DHEC) Bureau of Drug Control recently named Regina Erving, RPh, as director effective January 17, 2012. Erving has worked for the Bureau of Drug Control since 2002 as an inspector. She has extensive long-term care pharmacy experience as well as retail, hospital, and pharmaceutical sales. Erving has practiced pharmacy in Virginia, Ohio, and South Carolina. She graduated from Medical University of South Carolina in 1978 with a bachelor of science degree in pharmacy.

Erving sincerely encourages open dialogue with pharmacists, pharmacy technicians, interns, and practitioners related to the controlled substance statutes and regulations, in an effort to avoid potential confusion, misunderstanding, or violations. All of the Bureau of Drug Control staff welcome the opportunity to provide education and assistance with compliance. The Board and staff look forward to working with Erving in her new role.

2012 Board of Pharmacy Meeting Dates

The remaining Board of Pharmacy meetings will be June 13-14, 2012 and September 19-20, 2012. At its March meeting, the Board voted to change the date of the November meeting to Thursday, November 15, 2012. All meetings will be held at the Board's office located in the Synergy Business Park, Kingstree Building, 110 Centerview Drive, Columbia, SC.

South Carolina PMP Connects with NABP PMP InterConnect System

By Cheryl A. Anderson, RPh, Prescription Monitoring Program Director

Developed by the National Association of Boards of Pharmacy® (NABP®), the NABP PMP InterConnect℠ was designed to facilitate interoperability and interstate data sharing between state prescription monitoring programs (PMPs). The system was created at the request of several state PMPs to address a number of roadblocks states were experiencing in implementing a PMP data sharing solution. South Carolina actively participates as a member state of the NABP PMP InterConnect Steering Committee.

As a "rules engine" the NABP InterConnect ensures that each participating state's data access rules are enforced every time a request to the system is made. All data is encrypted during the transfer process and no data is stored in the NABP InterConnect.

The system became operational with data exchanges between Indiana and Ohio in August 2011. To date, 14 states have executed a memorandum of understanding (MOU) with NABP to participate and seven of those states – Connecticut, Indiana, Michigan, North Dakota, Ohio, **South Carolina,** and Virginia – are now live. An additional four states – Arizona, Kansas, New Mexico, and West Virginia – will be connected in late spring of 2012. In total, 20 states will either be connected to or working toward a connection to NABP InterConnect in 2012. Kentucky, Mississippi, and Utah have signed an MOU and the following PMPs have an MOU under review: Delaware, Louisiana, Montana, Nevada, North Carolina, Rhode Island, and South Dakota.

In the 200+ days since launching, the NABP InterConnect has processed 209,605 requests, with an average total wait time of 7.5 seconds for a consolidated multi-state PMP report. By enabling PMPs across the United States to be linked, NABP InterConnect provides a more effective means of combating drug diversion and drug abuse nationwide. Visit the NABP PMP InterConnect section of the NABP Web site at *www.nabp.net/programs* to access additional information about NABP InterConnect.

The *South Carolina Board of Pharmacy News* is published by the South Carolina 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.

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