June 2012

# Iowa Board of Pharmacy News

*Published to promote compliance of pharmacy and drug law*

400 SW 8th St, Suite E • Des Moines, IA 50309-4688 • Tel: 515/281-5944
Fax: 515/281-4609 • Web site: *www.state.ia.us/ibpe*

## Reminder Regarding Pharmacist CE Requirements

Pharmacists are reminded that in addition to 15 hours of Accreditation Council for Pharmacy Education (ACPE)-accredited drug therapy courses, they must now complete two hours of continuing education (CE) in **pharmacy law** and two hours of CE in **patient or medication safety** every two years (reference Rule 657, Iowa Administrative Code 2.12).

A total of 30 hours of CE every two years remains the minimum requirement for pharmacist license renewal.

To locate CE courses, pharmacists may check the P.L.A.N. Web site at *https://www.acpe-accredit.org/pharmacists/programs.asp.* Pharmacists should click on "Search P.L.A.N.® Now" to open the search page. They can then select their search options and click "Search."

*The CE in pharmacy law must be ACPE accredited. The CE inpatient/medication* safety may be either ACPE accredited or non-ACPE accredited. Non-ACPE accredited provider activities must be provided by an accredited health professional continuing education provider, such as a continuing medical education provider, and the activity content must directly relate to the pharmacist's professional practice.

- ACPE course identifiers in pharmacy law for pharmacists end with "L03-P."
- ACPE course identifiers in patient/medication safety for pharmacists end with "L05-P."

## New Patient Safety Task Force

In collaboration with the Iowa Pharmacy Association (IPA), the Iowa Board of Pharmacy is pleased to announce the formation of a new Patient Safety Task Force. The task force will be charged with creating a dialogue around the issue of patient safety and pharmacy work environments. The issue of patient safety is a key priority for both the Board and IPA. It crosses all pharmacy practice settings, including acute care, long-term care, community, and hospital. Issues will be addressed by stakeholders from all settings at both the practice level and the management level. The task force will meet as two subgroups throughout 2012 and will formulate recommendations to be presented in early 2013. The first meeting of the task force is scheduled for June 5, 2012.

## Board Member Retires

Pharmacist member **Mark M. Anliker, RPh,** of Emmetsburg, IA, retired from the Board on April 30, 2012. He served one three-year term, beginning on May 1, 2009. While on the Board, Mark also served on the Board's Rules Committee.

The Board extends its sincere thanks to Mark for his many contributions and his dedicated public service.

## Board Member Reappointed

Congratulations to pharmacist member **Susan M. Frey, RPh,** of Villisca, IA, who was reappointed by Governor Terry Branstad to her third three-year term on the Board effective May 2, 2012. Sue is employed by Hy-Vee Pharmacy in Red Oak, IA, and also serves as a consultant pharmacist for several long-term care facilities.

## New Board Member Appointed

Congratulations to pharmacist **Edward J. McKenna, RPh,** of Storm Lake, IA, who was appointed to a three-year term on the Iowa Board of Pharmacy by Governor Branstad effective May 1, 2012. Ed is a 1969 graduate of Creighton University School of Pharmacy and Health Professions. After owning and operating Lake Apothecary in Storm Lake for many years, Ed became a pharmacy manager for Hy-Vee in Storm Lake. He currently serves as president of the Storm Lake Board of Education. Ed replaces Mark Anliker on the Iowa Board of Pharmacy. The Board welcomes Ed and looks forward to working with him.

## Election of Board Officers

The Board has reelected **Susan Frey** as Board chairperson for a one-year term beginning May 1, 2012. **DeeAnn Wedemeyer-Oleson, PharmD, RPh,** was elected as vice chairperson for the same term.

## 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

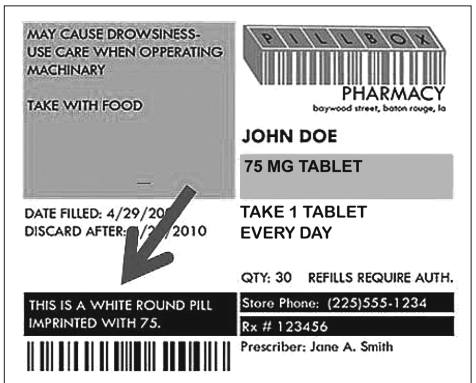
*This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies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

**Sue Mears, RPh,** of Urbandale, IA, began employment with the Board as a compliance officer on February 3, 2012. Sue is a graduate of Drake University College of Pharmacy and Health Sciences. Before joining the Board's staff, she worked as a pharmacist for 16 years in various practice settings including community pharmacy, mail order, and long-term care. Sue currently serves the Central Iowa area. She receives e-mail at Sue.Mears@iowa.gov.

## Board Clarification on Manufacturer's Coupons for Controlled Substances

At their meeting on April 27, 2012, the Board reviewed the rule regarding advertising prescription drug information by a pharmacy (reference Rule 657, Iowa Administrative Code 8.12). Because this rule specifically prohibits any reference to controlled substances in pharmacy advertising, the Board had interpreted this rule to prohibit the use of discount coupons toward the purchase of pseudoephedrine-containing products in Iowa.

Following review and discussion of the rule, the Board has amended its previous interpretation of this rule as it relates to original manufacturer's discount coupons for the purchase of controlled substances in Iowa. The Board has determined that, since the rule relates to pharmacy practices, the rule does not prohibit a manufacturer from offering or providing discount coupons for the manufacturer's controlled substances products.

Therefore, a pharmacy may honor a manufacturer's original discount coupon presented by a patient for the purchase of a controlled substance including a pseudoephedrine-containing product. A coupon that is obtained online is acceptable.

Pharmacists are reminded that when selling pseudoephedrine-containing products, the quantity and time restrictions imposed by federal and state laws and regulations must still be complied with.

## Board Calendar for 2012

The Board will hold regular Board meetings on the following dates (all meetings will be held at the Board office in Des Moines, IA):

- June 26-28
- August 28-29
- November 7-8

Meeting agendas will be posted on the Board's Web site. Dates are subject to change. Please contact the Board office at 515/281-5944 to confirm meeting dates.

## Board Web Site

Please visit the Board's Web site at *www.state.ia.us/ibpe/.*

## Board Mission

The Iowa Board of Pharmacy promotes, preserves, and protects the public health, safety, and welfare through the effective regulation of the practice of pharmacy and the licensing of pharmacies, pharmacists, and others engaged in the sale, delivery, or distribution of prescription drugs and devices. Iowa Code §155A.2(1).

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Lloyd K. Jessen, JD, RPh - State News Editor

Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor

Larissa Doucette - Communications Manager

IOWA BOARD OF PHARMACY

National Association of Boards of Pharmacy Foundation, Inc
1600 Feehanville Drive
Mount Prospect, IL 60056

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