



Iowa Board of Pharmacy

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 • Website: www.state.ia.us/ibpe

Board Members Reappointed

Iowa Board of Pharmacy members **Edward L. Maier**, **James A. Miller**, and **LaDonna Gratias** were reappointed by Governor Terry Branstad to additional three-year terms beginning May 1, 2014 and ending April 30, 2017. Ed Maier has been re-elected as Board chairperson and Jim Miller has been re-elected as Board vice chairperson, effective May 1, 2014 to April 30, 2015. The Board congratulates Ed, Jim, and LaDonna on their reappointments and thanks them for their continued public service.

PIC Advisory Committee

The following individuals have agreed to serve on a new Board of Pharmacy/Iowa Pharmacy Association advisory committee to review and revise pharmacist-in-charge (PIC) responsibilities and Board rules related to pharmacy ownership and the duties of pharmacy owners: **Cheryl Clarke**, Drake University, College of Pharmacy and Health Sciences, Des Moines, IA; **Brian Benson**, UnityPoint Health, Des Moines; **Cory Garvin**, Wester Drug, Muscatine, IA; **Angie Nelson**, Hy-Vee, Jefferson, IA; **Amanda Rosmann**, Walgreens, Ankeny, IA; **Dave Scofield**, Hartig Drug, Dubuque, IA; **Mike Fuller**, Walgreens, Ankeny; and **Edward McKenna**, Hy-Vee, Storm Lake, IA. The committee held its first meeting on May 13, 2014. It is anticipated that the committee will make recommendations to the Board and the Iowa Pharmacy Association before the end of 2014.

Iowa/NABP Pharmacy Inspection Project Results

The Board recently completed a special project in which nearly 80% of nonresident (out-of-state) pharmacies licensed to do business in Iowa were inspected. Between December 1, 2012 and December 31, 2013, a total of 538 nonresident pharmacies were surveyed with the assistance of the field services division of the National Association of Boards of Pharmacy® (NABP®).

The pharmacies that were inspected were located in 42 states. The top 10 states were:

- ◆ Florida: 69 pharmacies
- ◆ Illinois: 45 pharmacies
- ◆ Nebraska: 41 pharmacies
- ◆ California: 31 pharmacies
- ◆ Pennsylvania: 30 pharmacies
- ◆ Minnesota: 26 pharmacies
- ◆ Missouri: 22 pharmacies
- ◆ Tennessee: 21 pharmacies
- ◆ Texas: 20 pharmacies
- ◆ Ohio: 20 pharmacies

A total of 263 pharmacies (49%) were found to be engaged in some form of compounding. One hundred thirteen pharmacies (21%) were found to be doing both sterile and nonsterile compounding. Eighty-five pharmacies (16%) were doing only nonsterile compounding, while 65 pharmacies (12%) were doing only sterile compounding.

Of those pharmacies that were engaging in sterile compounding, the following was observed:

- ◆ High-risk preparations by prescription: 93 pharmacies
- ◆ High-risk preparations without a prescription: 40 pharmacies
- ◆ Medium-risk preparations by prescription: 121 pharmacies
- ◆ Medium-risk preparations without a prescription: 24 pharmacies
- ◆ Low-risk preparations by prescription: 134 pharmacies
- ◆ Low-risk preparations without a prescription: 23 pharmacies

In addition, 158 pharmacies (29%) were found to be performing bulk compounding without a prescription in anticipation of receiving prescriptions. There were 14 pharmacies that were also licensed as a distributor, with internal movement of compounded product from the pharmacy to the distributor.

These pharmacies ranged in size from 65 square feet to 163,000 square feet. The size of their compounding areas ranged from two square feet to 1,000 square feet.

The number of pharmacists per facility ranged from one to 258, while the number of pharmacy technicians ranged from one to 668. Some facilities dispensed up to 90,000 prescriptions per day. The number of prescriptions dispensed to Iowa patients ranged from one to 1,285 per day.

Interestingly, 47 of these same pharmacies (8.7%) were also inspected by Food and Drug Administration (FDA) during the same time period. Twenty-six of those pharmacies (4.8%) received a warning letter from FDA.

One hundred nine pharmacies (20%) were found to be operating under a waiver granted by their home state board of pharmacy. The types of pharmacies inspected included the following:

- ◆ Traditional retail/Community
- ◆ Health Maintenance Organization/Pharmacy Benefit Management only
- ◆ Institutional (hospital or long-term care)
- ◆ Mail order
- ◆ Central fill/Central processing
- ◆ Internet pharmacy
- ◆ Telepharmacy

The results of these inspections have been reviewed by the Board. In some cases, nonresident pharmacies have been issued letters of


Continued on page 4



New USP Webpage Answers Common Questions About USP Chapters <795> and <797>

In response to questions concerning United States Pharmacopeia-National Formulary (USP-NF) General Chapters <795> and <797>, USP has created a new frequently asked questions (FAQs) page on its website. The FAQs answer questions related to the Revision Bulletin for Chapter <795> that was issued on November 22, 2013, and became official on January 1, 2014. Among other topics, the FAQs address common questions regarding beyond-use dating and the differences between testing stability with strength (potency) or stability-inducing methods. The FAQs can be accessed at www.usp.org/support-home/frequently-asked-questions/compounding. Question four on the page includes a link to a USP article, "Strength and Stability Testing for Compounded Preparations."

Only You Can Prevent Look-Alike Sound-Alike Drug Names

 *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 Error Reporting Program. Report online at www.ismp.org. E-mail: ismpinfo@ismp.org.*

VESicare/Vesanoid Mix-Up. A prescriber's office sent an electronic prescription to the patient's pharmacy; the prescriber intended to prescribe **VESicare**® (solifenacin succinate) for overactive bladder but inadvertently selected **Vesanoid**® (tretinoin), which is used to induce remission of acute promyelocytic leukemia. The pharmacy technician entered the prescription for generic tretinoin; however, the pharmacy was unable to dispense the medication as the patient's pharmacy benefit manager required a prior authorization. The technician faxed a request and the prescriber's office replied back that VESicare was intended. Both of these products are available in 10 mg solid oral dosage forms, increasing the risk of confusion. Investigate strategies (eg, tall man letters) to differentiate these products on computer screens. Prescribers should include the indication for the drug with the prescription. As always, providing patient education, especially for new prescriptions, is a good strategy to intercept errors before they impact the patient.

Benazepril Confused With Benadryl. A pharmacist reported a mix-up between benazepril (**Lotensin**®) and **Benadryl**® (diphenhydramine). A patient faxed a request to the pharmacy to ask for her "benazpryl." The pharmacist who received the fax interpreted

it as Benadryl and placed a bottle of diphenhydramine in the bag for pick-up. Around this same time, the pharmacy went through a change in wholesaler and many manufacturers of generic products were changed. A few days later, a coworker of the patient picked up the medication (along with several others). The technician at the point-of-sale told the coworker that many of the manufacturers had changed recently and that some of the pills may look different. The patient received the diphenhydramine, filled her medication box with the capsules, and took diphenhydramine daily for three weeks before noticing she was unusually tired. When she brought the bottle back to the pharmacy, the error was recognized.

ISMP continues to receive reports of confused drug name pairs being involved in errors. ISMP wants to inform its readers of these drug name confusions so they may continue evaluating what measures they have in place to protect against these possible confusions.

Your Help Is Needed With Product Safety Testing. If you are a pharmacist, nurse, pharmacy technician, or other health care practitioner who is interested in furthering medication safety and error prevention, you can make a difference! Med-ERRS (a subsidiary of ISMP) is looking for assistance to help evaluate medication labels, drug packaging, and proposed drug names prior to submission by pharmaceutical and biotech companies for approval by Food and Drug Administration (FDA). The process is fun, simple, and easy. A small honorarium is paid. For more information or to sign up, visit www.med-errs.com and click on "Become a Reviewer."

FDA Issues Alert on Acetaminophen Products

In light of all the recent news alerts and warnings about the use of acetaminophen and acetaminophen-containing products, FDA issued a recommendation of importance to pharmacists, prescribers, and patients.

FDA recommends that health care providers consider prescribing combination drug products that contain 325 mg or less of acetaminophen. FDA also recommends that when a pharmacist receives a prescription for a combination product with more than 325 mg of acetaminophen per dosage unit that he or she contacts the prescriber to discuss a product with a lower dose of acetaminophen. A two-tablet or two-capsule dose may still be prescribed, if appropriate. In that case, the total dose of acetaminophen would be 650 mg (the amount in two 325 mg dosage units). When making individual dosing determinations, health care providers should always consider the amounts of both the acetaminophen and the opioid components in the prescription combination drug product.

FDA, in its MedWatch Safety Alert, reports that, "There are no available data to show that taking more than 325 mg of acetaminophen per dosage unit provides additional benefit that outweighs the added risks for liver injury. Further, limiting the amount of acetaminophen per dosage unit will reduce the risk of severe liver injury from inadvertent acetaminophen overdose, which can lead to liver failure, liver transplant, and death."

In January 2011, FDA asked manufacturers of prescription combination drug products containing acetaminophen to limit the amount of acetaminophen to no more than 325 mg in each tablet or capsule by January 14, 2014. FDA requested this action to protect consumers from the risk of severe liver damage that

Compliance News to a particular state or jurisdiction should not be assumed as representing the law of such state or jurisdiction.)



National Association of
Boards of Pharmacy
FOUNDATION

can result from taking too much acetaminophen. More than half of manufacturers have voluntarily complied with FDA's request. However, some prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit remain available. In the near future, FDA intends to institute proceedings to withdraw approval of prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit that remain on the market.

Boards of pharmacy have received inquiries from pharmacists about remaining stock of the higher dose acetaminophen and what procedures should be followed. The FDA recommendation notes that pharmacists are advised to contact prescribers and request a change in the prescription. If the prescriber is not willing to make the change in the prescription, unfortunately, there is no clear cut recommendation at this point as to whether to dispense the higher dose acetaminophen product. It would appear that the higher dose acetaminophen-containing products will be regarded by FDA as unapproved and delisted from FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book." Until this occurs, pharmacists must make a judgment regarding continuing to dispense the higher dose acetaminophen containing products in light of the FDA recommendation and concern for patient safety.

Some Rohto Eye Drops Products Recalled

The Mentholatum Company of Orchard Park, NY, has issued a voluntary recall of some Rohto® eye drop products due to a manufacturing review at the production facility in Vietnam involving sterility controls. The recall has been issued at the retail level and includes Rohto Arctic, Rohto Ice, Rohto Hydra, Rohto Relief, and Rohto Cool eye drops that were manufactured in Vietnam. Products made in other facilities are not affected by the recall. To date, there has been no evidence indicating the recalled products do not meet specifications, according to a press release.

The recalled products are sold over the counter at pharmacies and retail stores throughout the United States, and can be identified by the words "Made in Vietnam" on the side carton panel under the company name and address information as well as on the back label of the bottle. Lot numbers for the recalled products contain the letter "V." Distributors and retailers are being notified by letter to stop distributing the products and to follow the recall instructions provided by the company. Questions about the recall can be directed to The Mentholatum Company at 877/636-2677, Monday through Friday, 9 AM to 5 PM Eastern Time. FDA urges consumers and health care providers to report any adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information and Adverse Event Reporting Program. More information is available at www.fda.gov/Safety/Recalls/ucm382076.htm.

FDA Provides Compounding Law Implementation Information

FDA has provided implementation information on Title I of the recently passed Drug Quality and Security Act – known as the Compounding Quality Act – through its website.

Of note, FDA specifies that compounding entities may register as an outsourcing facility, which, under certain conditions, may be exempt from the Federal Food, Drug, and Cosmetic Act's (FD&C Act) approval and labeling requirements. Drugs produced by compounders that are not registered as outsourcing facilities must meet the conditions of Section 503A of the FD&C Act, which was amended by the new law, to qualify for certain exemptions.

The document adds, "If a compounded drug does not qualify for exemptions under either section 503A or 503B of the [FD&C Act], the compounded drug would be subject to all of the requirements of the [FD&C Act] that are applicable to drugs made by conventional manufacturers, including the new drug approval and adequate directions for use requirements." FDA also notes it will provide additional information about how the agency will interpret certain provisions of Section 503A at a later date.

The implementation information may be viewed at www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm375804.htm.

New e-LTP Fees Effective July 1, 2014

Supporting ongoing efforts to protect the integrity of its licensure transfer programs and to support the expansion of new technologies that are being implemented to enhance the program, the National Association of Boards of Pharmacy® (NABP®) is adjusting the fees for the Electronic Licensure Transfer Program® (e-LTP™).

Beginning July 1, 2014, the e-LTP fees will be adjusted as follows:

- ◆ The preliminary application and first state transfer fee will increase from \$350 to \$375
- ◆ Each additional state transfer will increase from \$50 to \$75
- ◆ Change of states will increase from \$50 to \$75
- ◆ Time extensions will increase from \$50 to \$75

The fees for e-LTP were last adjusted in 2010. More information about e-LTP is available in the Programs section of the NABP website at www.nabp.net. Additional questions about the fee adjustment may be directed to Neal Watson, licensure programs manager, at 847/391-4406, or at nwatson@nabp.net.



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

Continuing pharmacy education (CPE) providers who are accredited by the Accreditation Council for Pharmacy Education (ACPE) have integrated CPE Monitor® into their systems and are requiring pharmacists and pharmacy technicians to provide an NABP e-Profile ID number and date of birth (MMDD) in order to process ACPE-accredited CPE credit.

Visit www.MyCPEmonitor.net to set up your NABP e-Profile and register for CPE Monitor 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.

Continued from page 1

education or administrative warnings. In other cases, nonresident pharmacies have been issued a Statement of Charges and Notice of Hearing, which initiates the formal disciplinary process. More information will be released as it becomes available.

As of April 22, 2014, Iowa has 685 nonresident pharmacies actively licensed to do business in Iowa.

Dispensing Products Containing Pseudoephedrine Without a Prescription

The Board frequently receives inquiries regarding over-the-counter (OTC) sales of pseudoephedrine (PSE) products. Please note that pharmacies are **not** subject to single package limitations when selling OTC PSE products. Rule 657 IAC 10.32 provides all restrictions relating to PSE sales by pharmacies (emphasis added):

657 IAC—10.32 A product containing ephedrine, pseudoephedrine, or phenylpropanolamine, which substance is a Schedule V controlled substance and is not listed in another controlled substance schedule, may be dispensed or administered without a prescription by a pharmacist to a purchaser at retail pursuant to the conditions of this rule.

10.32(1) Who may dispense. Dispensing shall be by a licensed Iowa pharmacist or by a registered pharmacist-intern under the direct supervision of a pharmacist preceptor. **This sub-rule does not prohibit, after the pharmacist has fulfilled the professional and legal responsibilities set forth in this rule and has authorized the dispensing of the substance, the completion of the actual cash or credit transaction or the delivery of the substance by a nonpharmacist.**

10.32(2) Packaging of nonliquid forms. A nonliquid form of a product containing ephedrine, pseudoephedrine, or phenylpropanolamine includes gel caps. Nonliquid forms of these products to be sold pursuant to this rule shall be packaged either in blister packaging with each blister containing no more than two dosage units or, if blister packs are technically infeasible, in unit dose packets or pouches.

10.32(3) Frequency and quantity. Dispensing at retail to the same purchaser within any 30-day period shall be limited to products collectively containing no more than 7,500 mg of ephedrine, pseudoephedrine, or phenylpropanolamine; dispensing at retail to the same purchaser within a single calendar day shall not exceed 3,600 mg.

10.32(4) Age of purchaser. The purchaser shall be at least 18 years of age.

10.32(5) Identification. The pharmacist shall require every purchaser under this rule to present a current government-is-

sued photo identification, including proof of age when appropriate. The pharmacist shall be responsible for verifying that the name on the identification matches the name provided by the purchaser and that the photo image depicts the purchaser.

10.32(6) Record. Purchase records shall be recorded in the real-time electronic pseudoephedrine tracking system (PTS) established and administered by the governor's office of drug control policy pursuant to 657 IAC—Chapter 100 (the system commonly known as the NPLEx System).

Next Board Meeting

The Board plans to hold its next meeting at the Board office in Des Moines on **June 30 to July 2, 2014**. Administrative hearings and a closed session will be held on Monday, June 30, and Tuesday, July 1. The Board plans to meet in open session on Wednesday, July 2. Please contact the Board office at 515/281-5944 to confirm dates, times, and location.

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).

Board Website

Please visit the Board's website at www.state.ia.us/ibpe/.

Follow the Board on Facebook and Twitter



Facebook "Iowa Board of Pharmacy"

www.facebook.com/pages/Iowa-Board-of-Pharmacy/223126781053672



Twitter "IABoardPharmacy"

<http://twitter.com/#!/IABoardPharmacy>

Page 4 – June 2014

The *Iowa Board of Pharmacy News* is published by the Iowa 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.

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

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

Deborah Zak - Communications Manager