

May 2008



# Missouri Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

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## Final Notice

This is the **last** issue of the quarterly *Newsletter* that you will receive by mail. The Missouri Board of Pharmacy will discontinue printing and mailing the quarterly *Newsletter* following this publication. Future issues will be available via e-mail to all individuals who subscribe to the notification listing. To ensure you receive notification of the publishing of the *Newsletter*, you must subscribe to the listing. Please visit [www.nabp.net/indexmobop.asp](http://www.nabp.net/indexmobop.asp) and click the "subscribe" link. The Board's Web site also provides a link to this service.

## Technician Registration Renewal Deadline: May 31

All technician registrations **expire May 31, 2008**. If not renewed by this date, technicians cannot continue to work and must re-apply for registration by submitting a new, complete application and be re-fingerprinted. The pharmacist-in-charge is responsible for ensuring that all technicians working in the pharmacy are registered.

## Board Office Contact Information

Board office staff responded to nearly 10,000 telephone requests last year. These inquiries tie up a very small office staff and delay the processing of applications, issuing of licenses, and responding to questions. Whenever possible, please e-mail your questions concerning pharmacy laws, applications, and renewals instead of calling the office. The appropriate e-mail addresses to use depending on your subject matter are as follows:

Main Board office e-mail address and pharmacy licensure:

[pharmacy@pr.mo.gov](mailto:pharmacy@pr.mo.gov)

Questions concerning pharmacy laws and regulations:

[lawquestions@pr.mo.gov](mailto:lawquestions@pr.mo.gov)

Drug distributor licensure: [drugdistributor@pr.mo.gov](mailto:drugdistributor@pr.mo.gov)

Technician registration: [technician@pr.mo.gov](mailto:technician@pr.mo.gov)

Pharmacist licensure: [pharmacist@pr.mo.gov](mailto:pharmacist@pr.mo.gov)

Pharmacist intern licensure: [intern@pr.mo.gov](mailto:intern@pr.mo.gov)

## Licensing Action Report

### Pharmacists

**Steven H. Alvey, #45332** – St. Louis, MO – March 13, 2008.

Three (3) years probation. Failed employment drug test, did not have a valid prescription for substance for which he tested positive. Section 338.055.2(5), (6), (13), (15), and (17), RSMo.

**Darlene J. Atkinson, #43709** – Springfield, MO – February 16, 2008.

Three (3) years probation. Dispensed fraudulent prescriptions for personal use. Section 338.055.2(5), (6), (13), and (15), RSMo.

**Jeffrey C. Barnes, #40958** – Louisiana, MO – March 11,

2008. Two (2) years suspension, followed by five (5) years probation. August 2006 found guilty of one (1) count of felony stealing by deceit of at least \$500, and thirteen (13) felony counts of causing to be made a false statement to receive health care payments. Section 338.065, RSMo.

**Michelle Ann Darnell, #20080034643** – St. Louis, MO – February 1, 2008. Restricted pharmacist license issued on probation for five (5) years. Controlled substance addiction. Section 338.055.1 and .2(1), RSMo.

**Joseph M. Dicapo, #29071** – Kansas City, MO – February 8, 2008. Three (3) months suspension, followed by five (5) years probation. Acted as a wholesale drug distributor without a license, violation of drug laws and regulations, enabled two pharmacies to violate 4 CSR 220-5.020(1), established an account without employer's knowledge or approval, used the account to purchase drugs on behalf of his employer. Section 338.055.2(5) for incompetence, misconduct, fraud, misrepresentation, and dishonesty, (6), (13), and (15), RSMo.

**Roy H. Eberhart, II, #28133** – Eureka, MO – February 9, 2008. Probation for three (3) years. Pharmacist-in-charge failed to maintain complete and accurate controlled substance receipt/transfer records. Section 338.055.2(15), RSMo.

**Julie A. Hedgecorth, #41875** – St. Louis, MO – January 2, 2008. Suspended for six (6) months, followed by five (5) years probation. Impaired pharmacist, stole and consumed controlled substances while at work, pled guilty to felony stealing of a controlled substance. Section 338.055.2(1), (5), (13), (15), and (17); and 338.065, RSMo.

**Elisha K. Kirkpatrick, #2008003464** – Creve Coeur, MO – February 26, 2008. Restricted pharmacist license issued on probation until April 29, 2012. Disciplinary action in another state due to mental instability. Section 338.055.1 and .2(8), RSMo.

**Marion M. Kurz, #26813** – Springfield, MO – February 8, 2008. Revoked, cannot reapply for five (5) years. Found guilty of one count of second-degree assault, a Class C felony, in Greene County Circuit Court. Section 338.065, RSMo.

**Jerry H. Lopez, #2004035723** – Troy, IL – February 8, 2008. Probation for five (5) years. Impaired pharmacist. Section 338.055.2(1), (5), (13), (15), and (17), RSMo.

**John W. Morgan, #28330** – Cabool, MO – April 1, 2008. Probation for five (5) years. Controlled substance record-keeping violations, outdated/unlabeled medications in pharmacy stock, failure to maintain compounding logbook, technician dispensing

*Continued from page 4*



## **NABP Launches Pharmacy Curriculum Outcomes Assessment Program**

NABP launches its Pharmacy Curriculum Outcomes Assessment™ (PCOA®) mechanism in April 2008 for use by schools and colleges of pharmacy in evaluating their curricula. NABP invited schools and colleges of pharmacy to participate in the 2008 administration of the PCOA, scheduled for April 7-18. There will be no fee for participation in this first year of administration.

Those schools and colleges of pharmacy that participate in the April 2008 administration will receive detailed score reports for their students that sit for the assessment, as well as national comparative data. NABP developed the PCOA at the request of schools and colleges of pharmacy and accreditation stakeholders that have expressed a need for a national assessment that is psychometrically validated to assist with measuring curriculum development and student performance.

Details are posted under Assessment Programs on the NABP Web site, [www.nabp.net](http://www.nabp.net), or by contacting NABP Customer Service at [custserv@nabp.net](mailto:custserv@nabp.net).

## **An e-Educated Consumer is Your Best Customer (Patient)**



*This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and Food and Drug Administration (FDA) in analyzing 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 recommendations for prevention of reported errors that you can put into practice today, subscribe to **ISMP Medication Safety Alert!**® **Community/Ambulatory Edition** by visiting [www.ismp.org](http://www.ismp.org). If you would like to report a problem confidentially to these organizations, go to the ISMP Web site ([www.ismp.org](http://www.ismp.org)) for links with USP, ISMP, and FDA. Or call 1-800-23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org).*

According to the Pew Internet and American Life Project, Online Health Search 2006, 80% of American Internet users, or some 113 million adults, have searched for information on at least one of 17 health topics. Many Americans turn to the Internet before, or instead of, seeking information from their doctor or pharmacist. People want to make better decisions in their lives and therefore seek more in-depth research, research that is offered online.

Patients and caregivers have a vested interest to keep up-to-date on their own or their loved ones' medical conditions. The average doctor's appointment is just 10 minutes – hardly enough time to get into lengthy conversations about treatment options and medication side effects. Long lines, busy and distracted pharmacists, and lack of privacy and confidentiality deter patients from seeking more information from their community pharmacists. It is no wonder then, when patients do not understand medical terminology or want to explore the medication treatment options that are available, they do not call their doctor or pharmacist – they just log on. In the privacy of their home they can find practical information such as lists of foods they should or should not take with certain medical conditions or certain medications. Instead of bothering busy pharmacists

who do not appear to have the time to answer questions, they can get peace of mind when dealing with chronic conditions. They surf the net for reassurance and answers to their questions.

But what about the quality of those online sources? Some are better than others; obviously, Medline offered by the National Institutes of Health is a reliable source, but what if the site is sponsored by a pharmaceutical company? How does the consumer know which information to trust? Research suggests that most health information seekers do not check the source and date of the information they find online. Most Internet users use a search engine and key words from their own limited medical knowledge and rely on the algorithms of the search engines to find them reliable Web sites and scientific articles.

How can you, the pharmacist, help your patients find a credible health care information site? Patients need an easy-to-use, comprehensive medical Web site where they can learn about health conditions and medications. Patients should look for Web sites that offer unbiased health information written by medical professionals.

Tell patients to always check sources and dates of the information provided. For example, information on hormone replacement therapy has changed significantly in the last few years. Articles offering advice and recommendations on drug therapy from 10 years ago could be detrimental to the reader.

The patient-doctor-pharmacist triad has changed. We now live in an era of the square – the patient, doctor, pharmacist, and Internet. Help patients understand what they are reading. Go to the sites yourself and confirm the information is reliable and timely. And of course, find time to answer their questions. Look for a soon to be released consumer Web site being developed by ISMP.

## **FDA Warns against Using OTC Cold Medicines in Babies**

FDA issued a public health advisory on January 17, 2008, recommending that over-the-counter (OTC) cough and cold medicines should not be used to treat infants and children younger than 2 years of age, citing the risk of "serious and potentially life-threatening side effects." FDA held a public advisory committee meeting October 18-19, 2007, to discuss the issue, after which many pharmaceutical manufacturers voluntarily withdrew cough and cold medicines marketed for use in this age group.

FDA says the agency is in the process of evaluating the safety of OTC cough and cold medicines in children 2-11 years of age and will announce its recommendations "in the near future."

The public health advisory is available on the FDA Web site at [www.fda.gov/cder/drug/advisory/cough\\_cold\\_2008.htm](http://www.fda.gov/cder/drug/advisory/cough_cold_2008.htm).

## **Bayer Diabetes Care Recalls Contour Test Strips**

Bayer Diabetes Care recently recalled test strips (sensors) for use with the Contour TS Blood Glucose Meter. The company recalled the product because test strips from specific lots could result in blood glucose readings with a positive bias that could demonstrate 5% to 17% higher test results.

This issue is unrelated to the Contour TS meter itself and pertains only to certain test strips used with the meter. Strips used with other Bayer meters are unaffected.

Health care professionals are advised to check the lot number of the Contour test strips in their inventory and contact Bayer Diabetes Care for information on the return and replacement of strips.

More information is available in the manufacturer's press release at [www.fda.gov/medwatch/safety/2007/contourTS\\_recall.htm](http://www.fda.gov/medwatch/safety/2007/contourTS_recall.htm).



## **FDA Takes Action against Compounded BHRT Drugs**

FDA sent letters warning seven pharmacy operations that the claims they make about the safety and effectiveness of their so-called bio-identical hormone replacement therapy, or BHRT, products are unsupported by medical evidence, and are considered false and misleading by the agency. FDA has expressed concern that unfounded claims like these mislead women and health care professionals.

The pharmacy operations receiving warning letters use the terms “bio-identical hormone replacement therapy” and “BHRT” to imply that their drugs are natural or identical to the hormones made by the body. FDA regards this use of “bio-identical” as a marketing term implying a benefit for the drug, for which there is no medical or scientific basis.

The FDA news release is available at [www.fda.gov/bbs/topics/NEWS/2008/NEW01772.html](http://www.fda.gov/bbs/topics/NEWS/2008/NEW01772.html).

## **Manufacturers to Restrict Distribution of Methadone**

As of January 1, 2008, manufacturers of methadone hydrochloride tablets 40 mg (dispersible) have voluntarily agreed to restrict distribution of this formulation to only those facilities authorized for detoxification and maintenance treatment of opioid addiction, and hospitals. Manufacturers will discontinue supplying this formulation to any facility not meeting these criteria.

The 5 mg and 10 mg formulations indicated for the treatment of pain will continue to be available to all authorized registrants, including retail pharmacies. The 40 mg methadone formulation is indicated for the treatment of opioid addiction; it is not FDA-approved for use in the management of pain. This measure comes in response to the reported increase in methadone-related adverse events.

For more information, see “Studies Show Increased Methadone-Associated Mortality Related to Pain Management” in the January issue of the *NABP Newsletter*, available on the NABP Web site at [www.nabp.net](http://www.nabp.net).

## **New Compounding Standards Effective June 1; USP Offers Webinars**

New standards for sterile compounding will become effective on June 1, 2008. United States Pharmacopeia (USP) published the revised General Chapter 797, “Pharmaceutical Compounding – Sterile Preparations” on its Web site in December 2007 to give the compounding community time to implement changes before the effective date.

These revisions tighten standards and conditions for sterile compounding over the previous version of Chapter 797 to help improve patient safety. (See “Sterile Compounding ‘Checklist’ Revised to Better Protect Patient Health” in the February 2008 issue of the *NABP Newsletter*.) The revisions are included in USP 32–NF 27 and in the second edition of the *Pharmacists’ Pharmacopeia*, published in March 2008.

USP is offering a series of educational Webinars and workshops to help compounding professionals appropriately interpret and implement the newly revised standard. The Webinars will provide direct dialogue with two compounding experts and ample time to address questions related to the standard. The workshops will provide added interaction plus hands-on demonstrations related to environmental monitoring, contamination control, and aseptic testing.

Full details on these programs are available on the USP Web site at [www.usp.org/hottopics/generalChapter797.html?hlc](http://www.usp.org/hottopics/generalChapter797.html?hlc).

## **Moving? Need to Transfer Your License?**

It is easy – go to the Licensure Programs section of [www.nabp.net](http://www.nabp.net).

Questions? Call Customer Service at 847/391-4406.

*NABP – Serving Pharmacists with Licensure Transfer Since 1904*

## **CMS Names MSAs, Products for Round Two of DMEPOS Bidding**

Centers for Medicare and Medicaid Services (CMS) recently announced the metropolitan statistical areas (MSAs) and product categories for the second round of the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program.

All suppliers must meet quality standards and be accredited by a CMS-recognized accreditation organization, such as NABP, to obtain a contract under the Medicare DMEPOS competitive bidding program. The final deadline for all suppliers to obtain accreditation is September 30, 2009. However, CMS encourages suppliers to seek accreditation as soon as possible to avoid any potential difficulties that would affect their ability to bid.

The competitive bidding program is designed to improve the effectiveness of Medicare’s DMEPOS payments, reduce beneficiary out-of-pocket costs, and save the Medicare program money while ensuring beneficiary access to quality DMEPOS items and services. More information, including the lists of MSAs and product categories, is available on the CMS Web site at [www.cms.hhs.gov/CompetitiveAcqforDMEPOS](http://www.cms.hhs.gov/CompetitiveAcqforDMEPOS).

## **Adverse Event Reporting Requirements in Effect for OTC Products**

FDA recently issued new adverse event reporting requirements for manufacturers, packers, and distributors of dietary supplements and over-the-counter (OTC) drug products marketed without an approved application. The new reporting requirements, as described in Public Law 109-462, became effective on December 22, 2007.

The act, as well as the FDA *Guidance for Industry: Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed without an Approved Application*, is available via the FDA MedWatch site at [www.fda.gov/medwatch/otc.htm](http://www.fda.gov/medwatch/otc.htm).

## **FDA Rule Calls for Toll-Free Number for Adverse Events on Drug Labels**

FDA recently issued an interim final rule requiring certain medication labels to include a toll-free number for reporting adverse events. The interim final rule codifies provisions of the proposed rule “Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products” that became effective on January 1, 2008, under the FDA Amendments Act of 2007. The rule does not apply to over-the-counter medications approved as new drugs if the product packaging includes a manufacturer’s or distributor’s toll-free number for reporting complaints.

To allow manufacturers, dispensers, and pharmacies time to update their labeling and systems to comply with the new requirements, FDA will delay enforcement actions regarding these regulations until January 1, 2009.

More information is available in the *Federal Register* (Docket No. 2003N-0342) at [www.fda.gov/OHRMS/DOCKETS/98fr/E7-25426.pdf](http://www.fda.gov/OHRMS/DOCKETS/98fr/E7-25426.pdf).

without pharmacist supervision, reuse of prescription vials, and failure to produce evidence of required continuing education hours. Section 338.055.2(5), (6), (13), (15), RSMo.

**Santosh K. Reddy, #42629** – Olathe, KS – February 7, 2008. Probation for three (3) years. Compounding violations, failed to initiate a recall when product samples failed analysis, and pharmacy he owns operated without a pharmacist-in-charge. Section 338.055.2(5), (6), (13), and (15), RSMo.

**Mark P. Tyler, #44592** – St. Louis, MO – March 11, 2008. Revoked, cannot reapply for seven (7) years. August 2007 pled guilty to felony stealing a controlled substance. Section 338.065, RSMo.

**Interns**

**Jonathan P. Earley, #2008003461** – Kansas City, MO – February 1, 2008. Restricted intern license issued on probation for four (4) years. Pled guilty in 2000 to operating a motor vehicle while impaired with alcohol, and pled guilty in 2007 to assault in the third degree. Section 338.055.2(2), RSMo.

**Steven M. Gullette, #2008003835** – St. Louis, MO – November 23, 2007. Intern license issued on suspension for two (2) years, followed by probation for five (5) years. Theft of controlled substances from employer; in 2006 pled guilty to felony stealing a controlled substance. Section 338.055.1 and .2(1), (2), (5), (6), (15), and (17), RSMo.

**Pharmacies**

**Cabool Pharmacy, #3329** – Cabool, MO – April 1, 2008. Probation for five (5) years. Controlled substance record-keeping violations, outdated/unlabeled medications in pharmacy stock, failure to maintain compounding logbook, technician dispensing without pharmacist supervision, and reuse of prescription vials. Section 338.055.2(5), (6), (13), (15), and 338.285, RSMo.

**Eberhart Pharmacy, #003766** – St. Louis, MO – February 9, 2008. Probation for three (3) years. Failed to maintain complete and accurate controlled substance receipt/transfer records. Section 338.055.2(15), RSMo.

**Hillsboro Pharmacy, #2002005825** – Hillsboro, MO – February 9, 2008. Probation for three (3) years. Overfilled and mislabeled manufacturer containers in pharmacy inventory, misbranding, and failure to timely file pharmacist-in-charge change form. Section 338.055.2(6) and (15), RSMo.

**House Springs Pharmacy, #2002005822** – House Springs, MO – February 9, 2008. National Drug Code numbers altered, which resulted in misbranding. Section 338.055.2(15), RSMo.

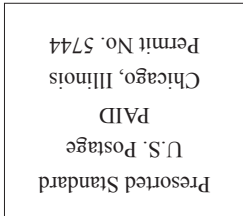
**Medicine Shoppe, #005742** – Blue Springs, MO – February 7, 2008. Probation for three (3) years. Compounding violations, failed to initiate a recall when product samples failed analysis, operated without a pharmacist-in-charge. Section 338.055.2(5), (6), (13), and (15), RSMo.

**Shark Pharmacy, #005897** – Florissant, MO – February 18, 2008. Voluntary surrender of pharmacy permit, cannot reapply for seven (7) years. Repeatedly allowed and fed a dog in the pharmacy while conducting pharmacy services, failed to maintain the pharmacy in a clean and sanitary condition. Section 338.055.2(5), (6), (15); and 338.285, RSMo.

**Walgreens #01235, #2004020210** – Warrensburg, MO – February 8, 2008. Probation for two (2) years. Operated without a pharmacist-in-charge, failed to complete controlled substance inventory with changes of pharmacist-in-charge. Section 338.055.2(6) and (13), RSMo.

The *Missouri Board of Pharmacy News* is published by the Missouri Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary 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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