

June 2008



# Kansas State Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

## Fifty Years of Service

Congratulations to the following pharmacists who were honored in 2007 for completing 50 years of continuous licensed service to the citizens of Kansas and the profession of pharmacy. The Kansas State Board of Pharmacy is grateful for their years of contribution to the profession.

Allen L. Asher .....	Paola, KS
Martin J. Swisher .....	Gardnerville, NV
Darrel L. Stone .....	Overland Park, KS
Robert P. Renick .....	Garden City, KS
Donald R. Price.....	Canoga Park, CA
Ronald L. Montgomery .....	Ellsworth, KS
Theodore G. Mariani .....	Eureka, KS

## Board Members Reappointed

Congratulations to Shirley Arck, PharmD, of Manhattan, KS, who was reappointed to a three-year term on the Kansas State Board of Pharmacy by Governor Kathleen Sebelius effective April 30, 2008. Dr Arck received her bachelor of science in pharmacy (1981) and doctor of pharmacy (2003) degrees from the University of Kansas School of Pharmacy and has been a licensed pharmacist in Kansas since 1981. Dr Arck is certified in pain management and adult immunization administration and is employed as the hospital administrator and acting director of pharmacy at the Kansas State University Veterinary Medical Teaching Hospital in Manhattan. She is also currently serving as the Board's vice president.

Congratulations also to Michael Coast, RPh, of Cimarron, KS, who was reappointed to a three-year term on the Kansas State Board of Pharmacy by Governor Sebelius effective April 30, 2008. Mike received a bachelor of science degree in accounting from Saint Mary of the Plains College in Dodge City, KS, and a bachelor of science degree in pharmacy from the University of Kansas School of Pharmacy. A practicing pharmacist since 1995, Mike is the pharmacist-in-charge at Clark Pharmacy, Inc, in Cimarron, KS, and a consultant to numerous area hospitals, nursing homes, and hospices. Mike is also a certified geriatric pharmacist and is currently serving as the Board's president.

The Board welcomes Shirley and Mike and looks forward to continuing to work with these accomplished pharmacists during the next three years.

## 2008 Legislative Changes

The Kansas legislature passed several important pharmacy-related bills during the 2008 session. Senate Bill (SB) 491 creates the Prescription Drug Monitoring Program (PMP) recommended

by the Prescription Monitoring Task Force that met over the last six months pursuant to a proviso from the 2007 legislative session. The task force was chaired by Barry Sarvis, RPh, and included many stakeholders from the health care community who participated in developing the recommendation. SB 491 requires the Kansas State Board of Pharmacy to establish and maintain a PMP for Schedule II through IV substances. Each dispenser of outpatient drugs is required to electronically submit information for each controlled substance prescription dispensed to the Board of Pharmacy. The Board of Pharmacy is required to develop and maintain a database of controlled substance prescriptions submitted. The database will be confidential and access is limited to certain persons authorized by the statute including pharmacists and prescribers. The PMP will have an advisory committee from various disciplines to advise the Board on its operations. The Board has applied for a grant from the United States Department of Justice to help implement the program. The Board will provide education to the pharmacies once rules and regulations for the program are promulgated and it is operational.

The bill also requires the Board of Pharmacy to assemble a task force to study the feasibility of scheduling pseudoephedrine products as a Schedule III or IV controlled substances. The study is to consider the impact on the consumer and any costs associated with making such a change. The task force is required to report its findings to the 2009 legislature.

SB 549, the bill that creates a continuous quality improvement program (CQI) for retail pharmacy was amended into SB 491 and must be in place no later than July 1, 2009. The purpose of the CQI program is to assess errors in dispensing or furnishing prescription medications so that the pharmacy may take appropriate action to prevent a recurrence. Any reports, memoranda, proceedings, findings, or other records generated as part of the CQI program are considered confidential and privileged peer review documents and not subject to discovery, subpoena, or other means of legal compulsion for their release. Such information will not be admissible in any civil or administrative action other than an administrative proceeding initiated by the Board of Pharmacy. Nothing in the new statute should be construed to prevent a patient from accessing such patient's prescription records, nor does confidentiality affect the discoverability of records that are not generated or maintained solely as part of a CQI program. The Board will promulgate rules and regulations that will require the pharmacy to keep records of its CQI meetings. Once a meeting has been held the pharmacy must create a summarization document that contains an analysis of remedial measures that will be undertaken following an event. The intent

*Continued on page 4*



# National Pharmacy

(Applicability of the contents of articles in the National Pharmacy Compliant  
and can only be ascertained by examining t

## **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 [cust-serv@nabp.net](mailto:cust-serv@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).

# Compliance News

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the law of such state or jurisdiction.)



## 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).

*Continued from page 1*

of the CQI bill is for the pharmacy to prevent future medication-related problems or errors.

The second portion of SB 549 provides an additional remedy to the Board of Pharmacy to assess a civil fine against a nonresident pharmacy not exceeding \$5,000 per violation when a nonresident pharmacy fails to supply information requested by the Board or to respond to an inquiry after being noticed by certified mail.

The legislature also placed three substances on the Schedule I controlled substance list in Kansas. These include salvia divinorum (salvinorum A), datura stramonium (gypsum weed or jimson weed), and 3, 4-methylenedioxymethamphetamine (Ecstasy).

House Bill (HB) 2578 creates the Utilization of Unused Medications Act, a voluntary program through which adult-care homes, mail-service pharmacies, and medical-care facilities may donate unused medications to indigent health care clinics, federally qualified health centers, or community mental health centers for distribution to medically indigent Kansas residents. The bill would establish criteria for which medications can be donated including that medications must come from a controlled storage unit of the donating entity, be either in its original sealed unit dose packaging or in a hermetically sealed tamper-evident package, the medication must be nonexpired, and controlled substances cannot be donated. The Board of Pharmacy will establish and implement the Unused Medication program and provide technical support assistance to entities who wish to participate. The Board will promulgate rules and regulations by December 2008 for program implementation by December 1, 2008.

HB 2618 did not pass this session, but may be introduced again next year. The bill would require the Board of Pharmacy and other state agencies to use the Office of Administrative Hearings for conducting all disputed hearings under the Kansas Administrative Procedure Act. The Office of Administrative Hearings would assign an attorney to hear cases rather than the Board of Pharmacy. The presiding officer would render an initial order that would become a final order unless reviewed. The bill would have required the licensee or registrant to provide an expert witness for the hearing at their own expense. The legislature will be reviewing this for all administrative agencies again next year. You may review HB 2618 in its entirety online at [www.kslegislature.org](http://www.kslegislature.org). If you oppose any part of HB 2618, you may want to consider contacting your representative and senator to let them know your position.

## ***Issuance of Multiple Prescriptions for Schedule II Controlled Substances***

Drug Enforcement Administration has clarified that there is no federal limit on the amount of controlled substances a practitioner can legitimately prescribe. There is also no state limitation. However, if a practitioner issues multiple prescriptions for a Schedule II it must be no more than a 90-day supply. It is up to the practitioner to determine how many separate prescriptions are to be filled sequentially as needed to provide for adequate medical care. For example, a practitioner may issue three 30-day Schedule II prescriptions to cover a 90-day supply or he or she may issue nine prescriptions for the same Schedule II controlled substance, each for a 10-day supply, having the combined effect of a 90-day supply. For more information on the issuance of multiple prescriptions for Schedule II substances visit [www.deadiversion.usdoj.gov](http://www.deadiversion.usdoj.gov).

## ***Disciplinary Actions***

**Noel McBride**, Pharmacist – License #1-14109 License Revoked

**Corey Gene Farley**, Pharmacy Technician – Reg #14-03394 License Revoked

**Cindy L. Mares**, Pharmacy Technician – Reg #14-06398 License Revoked

**Shawwnna L. Marrs**, Pharmacy Technician – Reg #14-03421 License Revoked

**Angela Walts**, Pharmacy Technician – #14-04891 Revoked

**Heather Williams**, Pharmacy Technician – #14-06836 License Revoked

**Lindsay Nicole Manning**, Pharmacy Technician – #14-02790 License Revoked

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