June 2008

Kentucky Board of Pharmacy

NEWS

Published to promote voluntary compliance of pharmacy and drug law.

Spindletop Administration Building
2624 Research Park Dr, Suite 302
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Pharmacy Renewal Deadline June 30, 2008

Pharmacy permits expire June 30, 2008. A pharmacy permit can be renewed online. A postcard explaining the renewal process was mailed to each pharmacy on April 25, 2008. If you want to send in a paper renewal, this form may be printed from the Kentucky Board of Pharmacy's Web site: *www.pharmacy.ky.gov*. If you have any questions concerning the renewal process please contact the Board office. Please be reminded that if your pharmacy address changed, relocated within the current premises of the existing permit, or changed ownership, you must complete a new pharmacy application. A pharmacy application with a United States Post Office Box address only will **not** be accepted and will be returned. All incomplete applications will be returned. Remember the deadline is June 30, 2008. All paper renewal applications must be in the Board office by the close of the day June 30, 2008.

Legislation Update 2008

House Bill (HB) 328 (sponsored by Representative Susan Westrom) passed the House and Senate and was signed into law by Governor Steve Beshear on April 25, 2008.

HB 328 requires the simple registration and a $25 fee of pharmacy technicians by April 1, 2009. The Board of Pharmacy has begun the development phase of the registration process. Information will be provided to pharmacy technicians, pharmacies, and pharmacists as this process is developed.

HB 541 (sponsored by Representative Tom Burch), which was a bill that would direct an interim study on the role that pharmacists play in the health care system, passed the House; however, the Senate failed to act on this bill.

Senate Bill (SB) 118 (sponsored by Senator Julie Denton) passed the House and Senate and was signed into law by Governor Beshear on April 15, 2008. This bill creates a new section of KRS 315 regarding wholesalers (which deletes the wholesaler requirements of KRS 315.036). This bill also creates legislation regarding drug pedigree. The Board is required to promulgate regulations regarding this new law and will begin to develop them.

Psuedoephedrine Sales Electronically

Submitted by Van Ingram, Compliance Branch Manager, Kentucky Office of Drug Control Policy

The passage of SB 88 in 2007 allowed the Commonwealth of Kentucky to link all pharmacies in the Commonwealth to one centrally located database. By linking together into one database, each pharmacy's psuedoephedrine (PSE) related transaction information will be captured for the purpose of preventing methamphetamine production. With this system in place, both law enforcement and pharmacies benefit significantly. Pharmacies will benefit by having a system that automatically limits the amount of PSE products sold to each customer, based on both state and federal purchase requirements, thus keeping pharmacies in full compliance with the law. Law enforcement will benefit by having an investigative tool that allows them to track those customers attempting to violate PSE restrictions. It should be noted that this only applies to retail over-the-counter sales of PSE in tablet or caplet form. Those pharmacies that only dispense PSE by prescription are automatically exempt.

The Kentucky Office of Drug Control Policy selected MethCheck™, powered by Appriss, Inc, to provide this electronic PSE monitoring solution. To effectively achieve our deployment schedule and to fulfill the requirements listed in 906 KAR 1:160, all pharmacies in the state must agree to comply with the electronic reporting requirements by June 1, 2008.

In order to accomplish a statewide deployment rollout by this date, Appriss will work with the corporate contacts of most major pharmacy chains in the state to develop an application programming interface (API) that will extract limited PSE transaction information from each chain pharmacy. Appriss will also set up user accounts for all independent (and some chain) pharmacies to use its MethCheck Rx Web portal application. With this application all that is required is a computer and an Internet connection; there is no hardware or software to install. MethCheck Rx is Appriss' Web-based solution for gathering limited PSE transaction information. With these two methods, API and MethCheck Rx, all pharmacies in the state will be set up to submit PSE transaction information to MethCheck.

Continued on 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,* or by contacting NABP Customer Service at 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. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (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.*

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.*

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.*

Compliance News

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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.*

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.*

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.*

Moving? Need to Transfer Your License?
It is easy – go to the Licensure Programs section of *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.*

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.*

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.*

Continued from page 1

To assist pharmacies with training on MethCheck Rx and with general MethCheck support-related questions, Appriss and the Office of Drug Control Policy provided regional training sessions for all pharmacies in eight locations around the state.

If you attended one of those earlier trainings or have been in contact with our office, you know that the signature requirement issue had not been finalized. We are pleased to report that the issue has been addressed by the Drug Enforcement Administration. It has determined that a pharmacy **will** be compliant with the Combat Methamphetamine Epidemic Act (CMEA) if it enters the customer and purchase data electronically into the MethCheck Rx system and maintains a paper log of signatures. This paper log need only contain the transaction number generated by the MethCheck Rx system and the customer's signature. We would encourage you to use the signature paper provided by the MethCheck system. You can find these printable forms under the **Help** tab of the system. Just click on **Signature Slips** and then click the **Signature Pad** link located at the bottom of the page. The slips can be printed anytime as needed.

Pharmacies that wish to begin using the MethCheck Rx system before the June 1, 2008 deadline can begin immediately and will not be responsible any longer to maintain the paper log books, except for the signature log. In order to comply with the CMEA, you must still keep each signature on file for at least two years. We recommend that you keep each page of the signature slips on file in a binder for future reference. This way, the signature slips can be maintained in a secure environment, at the store location where the transaction occurred. It is recommended that logs be maintained in a secure environment, at the store location where the transaction occurred.

Please note that there is no financial cost to your pharmacy for participating in this project. It is funded by the Cabinet for Health and Family Services, Office of Inspector General Professional Standards Branch. Unless granted an exemption in accordance with KRS 218A.1446(2)(b), your participation is required as a result of the regulations that have been passed. By taking part in the project, you are contributing to the overall success of eliminating methamphetamine lab production in communities around the Commonwealth.

If you need additional information or assistance please contact Office of Drug Control Policy at 888/417-6327.

Board Address

The Board is constantly receiving important documents mailed to our old addresses at Millcreek Park and Capital Center Drive. This may cause a licensee or permit holder not to receive their license, their permit, or vital information in a timely manner, which may result in action taken against a licensee or permit holder. Examples: renewing a license or permit on time, notification of a pharmacist-in-charge, or fulfilling the requirements of an agreed order. Please review all your records, including any forms and payment systems, to make sure that you are using the correct Board of Pharmacy address. The correct address is:

Kentucky Board of Pharmacy
Spindletop Administration Building, Suite 302
2624 Research Park Dr
Lexington, KY 40511

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