

May 2008



Arkansas State Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

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Pseudoephedrine Tracking

The following letter was sent to retail pharmacies in the state of Arkansas in mid-February outlining Arkansas Act 508 of 2008. The Arkansas State Board of Pharmacy would like to encourage pharmacies to work with the Arkansas Crime Information Center on this endeavor as it serves to protect the public health and welfare.

Arkansas Crime Information Center

To Arkansas Pharmacies:

As you may know, Act 508 of the 86th meeting of the Arkansas General Assembly requires the Arkansas Crime Information Center (ACIC) to provide a real-time electronic logbook for all pharmacies throughout the state of Arkansas to record purchases of ephedrine, pseudoephedrine, and phenylpropranolamine. **There is no cost to pharmacies for the service.**

The real-time electronic logbook is designed to reduce and ultimately eliminate the manufacture of methamphetamine in Arkansas. All pharmacies in Arkansas are required and will be equipped to enter transactions of the sale of products containing these substances into the logbook. ACIC will maintain and control access to the electronic logbook, allowing authorized criminal justice officials to access the data for the investigation of crimes involving the illegal manufacture of methamphetamine in accordance with Act 508.

Act 508 is currently in effect, and the electronic logbook must be fully deployed in all pharmacies on or before May 15, 2008. Our goal is to provide a user-friendly experience and streamline compliance reporting for you and your staff.

LeadsOnlabs has been selected to provide the electronic logbook and to help you bring your pharmacy online. You may enter transactions via an online portal provided by LeadsOnlabs. If your pharmacy has a system in place for collecting this information, LeadsOnlabs will provide an interface to link your system with the electronic logbook. LeadsOnlabs will contact you in the coming weeks with instructions on how to implement and use the electronic logbook.

Thank you in advance for your participation as we work together to promote health and public safety in Arkansas. If you have questions, you may call me at 501/682-2222 or LeadsOnlabs at 888/994-7771.

Sincerely,

Charlie Pruitt, Director

Combat Methamphetamine Epidemic Act

Please remember that self certification through Drug Enforcement Administration (DEA) for selling pseudoephedrine and ephedrine containing products must be renewed annually. This can be completed through the DEA Web site at www.deadiversion.usdoj.gov/meth/index.html.

Regulation Changes from February Meeting

After the adoption of an emergency regulation during October 2007 regarding proper practitioner-patient relationships, the following regulation was adopted on a permanent basis during the February Board meeting following public comments.

07-00-0009 – Proper Practitioner-Patient Relationship

In accordance with Ark. Code Ann. § 17-92-1004(c) and Ark. Code Ann. § 17-92-1003(15), an in-person physical exam of the patient performed by a practitioner, physician, doctor or other prescribing health professional (“a practitioner”) prior to the issuance of any prescription is required in order to establish a valid prior patient-practitioner relationship for purposes of Ark. Code Ann. § 17-92-1004(c) and a “Proper Physician-Patient Relationship” for purposes of Ark. Code Ann. § 17-92-1003(15), unless:

- (a) the prescribing practitioner is consulting at the specific request of another practitioner who:
 - (1) maintains an ongoing relationship with the patient;
 - (2) has performed an in-person physical exam of the patient; and
 - (3) has agreed to supervise the patient’s ongoing care and use of prescribed medications; or
- (b) the prescribing practitioner interacts with the patient through an on-call or cross-coverage situation. (Emergency 10/31/2007, 2/25/2008)

License/Permit Renewals

After closing the renewal period for pharmacies and pharmacists on April 1, a review of our records indicates that 65% of pharmacists and pharmacies used the Board of Pharmacy Web site to renew their permits or licenses. Through this process, 48,827 continuing education records were reported electronically. Most people who renewed online were able to have renewals processed within one to two business days and obtained new permits within a week of submitting renewals.

Change of Employment Status

Board staff continues to find examples of pharmacists, technicians, and interns who do not have correct contact addresses or employment information updated with the Board of Pharmacy. Notification of these changes is required for pharmacy technicians, interns, and pharmacists. Both the employee and employer are required to notify the Arkansas State Board of Pharmacy of any employment status changes. This applies to numerous pharmacy employment settings including retail/community pharmacy, hospital pharmacy, nuclear pharmacy, and nursing home consulting. The Board of Pharmacy has tried to address this issue numerous times through the use of this *Newsletter* and other means. At this point, Board staff will pursue action for failure to appropriately notify

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.



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

the Board of employment changes and changes in contact information. The following regulations help to address this issue:

02-00-0001 – Changes In Employment

Whenever any licensed pharmacist shall change his place of employment for any reason, it shall be the duty of the former and current employer and said licensed pharmacist to notify the Arkansas State Board of Pharmacy in writing of such change within five days after such change of employment. Notification must be made by letter, fax, or email and must contain the new place of employment of the licensed pharmacist, his license number, and his renewal number.

03-00-0002 – Registration Required

- (f) When a pharmacy technician leaves the employment of a pharmacy, the pharmacist in charge shall notify the Board, in writing, within fourteen (14) days.
- (g) Any concurrent or subsequent employment at any pharmacy shall be reported to the Board of Pharmacy by both the pharmacy technician and the pharmacist in charge of the pharmacy where the pharmacy technician will be working. The pharmacist in charge must notify the Board of Pharmacy, in writing, of the exact date when the pharmacy technician will begin working. The pharmacy technician shall not work at that location until the Board of Pharmacy has received said notification.

A Reminder from CMS – Medicaid Tamper-Resistant Prescription Law Became Effective on April 1

The Medicaid tamper-resistant prescription requirements became effective beginning April 1, 2008. The law applies only to written prescriptions for covered outpatient drugs; prescriptions that are transmitted from the prescriber to the pharmacy verbally, by fax, or through an e-prescription are not impacted by the statute, and so those methods may be used as alternatives to a written prescription. The law applies whenever Medicaid pays any portion of the cost of a prescription. To be considered tamper resistant on April 1, 2008, a prescription pad must contain **at least one** of the following three characteristics:

1. one or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form;
2. one or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription pad by the prescriber;
3. one or more industry recognized features designed to prevent the use of counterfeit prescription forms

By October 1, 2008, a prescription pad must contain **all three** of the above characteristics to be considered tamper resistant. Check the following links for more information: www.cms.hhs.gov/DeficitReductionAct/Downloads/tamperapril1.pdf or <https://www.medicaid.state.ar.us/InternetSolution/Provider/newprov.aspx#rxpads> or call Arkansas Medicaid at 501/683-4120.

Scanning Prescriptions

As a reminder, during the August 2005 Board of Pharmacy meeting the Board discussed prescription scanning technology and specifically addressed the subject of who could scan prescriptions into the computer database in pharmacies where this technology is being utilized. After discussing the practice of allowing non-licensed personnel (pharmacy clerks) to scan prescriptions into the computer system, the Board decided to only allow licensed or registered personnel (pharmacists, interns, and pharmacy technicians) to scan prescriptions into the computer and not to allow clerks to perform this function.

Special Notice about the Arkansas State Board of Pharmacy Newsletter

The Arkansas State Board of Pharmacy has designated this *Newsletter* as an official method to notify pharmacists licensed by the Board about information and legal developments. Please read this *Newsletter* and keep it for future reference because this Newsletter will be used in hearings as proof of notification of the *Newsletter's* contents. Please contact the Board office (501/682-0190) if you have questions about any of the articles in this *Newsletter*.

**Arkansas Pharmacy Support Group Help Line
870/636-0923**

Page 4 – May 2008

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