



Arkansas State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

101 E Capitol, Suite 218 • Little Rock, AR 72201 • Tel: 501/682-0190 • Fax: 501/682-0195

Monitor, Secure, and Dispose – DEA to Host National Drug Take-Back Day September 25, 2010

The Arkansas State Board of Pharmacy is proud to share that in June, Drug Enforcement Administration (DEA) announced a national drug take-back initiative planned for September 25, 2010. In their letter to the state, they describe the ongoing issue of prescription drug abuse on the national level and are supporting this nationwide effort through local law enforcement to encourage people to properly dispose of expired and unused medications. The Board is hopeful that this will act as a catalyst for programs all over the state on this date and hopes you will encourage the patients from your workplace to participate in these events.

It is vital to help people increase awareness regarding what medications they have in their homes, inform them how to secure their medications, and inform them how to appropriately dispose of their medications when they are no longer needed. These three steps could help prevent countless problems and potential injuries or death from prescription drug abuse. Please refer to the Web site, www.ioit2me.com, for information regarding drug abuse that may be beneficial to parents and teens. You

can also help educate patients on the SMARxT Disposal program, which they can follow at any time to dispose of their medications at home.

For more information, please visit www.ioit2me.com and www.smarxtdisposal.net.

Narcotics Task Force Control and Detection Committee Report

The Arkansas State Board of Pharmacy appointed a Board committee of pharmacists from various areas of practice to highlight issues related to diversion as the Narcotics Task

Force for Control and Detection. This committee's report was discussed during the June 2010 Board meeting where the Board was able to consider different approaches to both prevent and detect diversion of controlled substances. A few of these measures that can be instituted in most any pharmacy would include the following:

- ♦ In and out report during a routine time frame (shrink report, check of how much ordered vs how much dispensed in a specific time frame such as 1, 3, 6, 9, or 12 months)
- ♦ Quarterly audits for selected products, such as medications at high risk for diversion or abuse
- ♦ Perform annual inventory (or more frequent) for controlled substances to verify on-hand quantities of each medication
- ♦ Routinely run report on changes made to inventory in dispensing system and check for validity of changes

These detection measures were discussed as well as potential regulation changes that the Board has requested for consideration during the October Board meeting, which would include adding responsibility to the pharmacy permit holders for having policies and systems in place for preventing and detecting diversion of controlled substances, as well as clarifying requirements for pharmacists to utilize these tools.

DEA Request for Comments

DEA is requesting input regarding the dispensing of controlled substances for residents of long-term care facilities (LTCF) as outlined in the *Federal Register*. Specifically, DEA is seeking comments from practitioners, pharmacists, LTCFs, nurses, LTCF residents, and families of residents on how DEA regulations might be modified to make it easier for LTCF residents to gain access to controlled medications. The *Federal Register* notice is available at <http://edocket.access.gpo.gov/2010/pdf/2010-15757.pdf> and states in part:

Department of Justice

Drug Enforcement Administration

[Docket No. DEA-337N]

Dispensing of Controlled Substances to Residents at Long Term Care Facilities

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

Continued on page 4



FDA Updates 'Medicines in My Home' Patient Education Resources

Food and Drug Administration (FDA) has updated the Medicines in My Home (MIMH) section of the agency's Web site with new resources and materials for patients. MIMH resources teach patients from adolescence through adulthood how to choose over-the-counter (OTC) medicines and how to use them safely. An interactive video teaches users how to understand the drug facts label and make sound medicine decisions. Downloadable documents provide information on caffeine use, choosing appropriate OTC medications, and other related topics. The MIMH Web page can be accessed at www.fda.gov/Drugs/Resources/ForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingOver-the-CounterMedicines/ucm092139.htm.

DEA Releases e-Prescription for Controlled Substances Interim Final Rule

The Drug Enforcement Administration (DEA) Interim Final Rule on electronic prescriptions for controlled substances was published in the *Federal Register* on March 31, 2010, and was scheduled to go into effect June 1, 2010, subject to Congressional review. The regulations would allow prescribers the option to write prescriptions for controlled substances electronically, and allow pharmacies to receive, dispense, and archive these electronic prescriptions. The regulations are an addition to existing rules, and include stipulations to ensure that a closed system of controls on controlled substances dispensing is maintained. The regulations have the potential to reduce prescription forgery and reduce the number of prescription errors, and should also reduce paperwork and help integrate prescription records into other medical records.

Confirmation Bias



This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency 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 is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also a FDA MedWatch partner. Call 1-800-FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at www.ismp.org. ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Although pharmaceutical companies and regulatory agencies have been working on design changes to improve the situation, ISMP still associates many medication errors with confusion over "look-alike" or "sound-alike" product names. Since patients receive the wrong drug, these sometimes result in serious harm. A common cause of name mix-ups is what human factors experts call "confirmation bias." Confirmation bias refers to a type of selective thinking whereby individuals select what is familiar to them or what they expect to see, rather than what is actually there.

Many errors often occur when pharmacists or technicians, due to familiarity with certain products, see the name of the product they think it is rather than what it actually is. For instance, if a pharmacist reads a poorly written drug name, he or she is most likely to see a name that is most familiar to him or her, overlooking any disconfirming evidence. Another example of this is if a pharmacy technician chooses a medication container based on a mental picture of the item, whether it is a characteristic of the drug label, the shape, size, or color of the container, or the location of the item on a shelf.

Although various compilations of look-alike name pairs are available for posting (see www.ismp.org/Tools/confuseddrugnames.pdf for ISMP's List of Confused Drug names, which has recently been updated), these lists have only limited usefulness since it is impossible for practitioners to memorize them in order to know when to check on questionable prescriptions. Also, when confirmation bias occurs, there is never a reason for the practitioner to question the order to begin with.

In many cases, hospital or pharmacy computer systems can be used to reduce the risk of confirmation bias and resulting name mix-ups. Many systems have a "formulary note" field that can be easily adapted to display important information prominently on the computer screen. Similar to a road sign warning about a dangerous intersection ahead, this feature can be used to alert the person inputting the medication when a look-alike or sound-alike danger is present. For example, when *Norvase*® is entered into the computer, a formulary note screen appears, alerting the pharmacist that *Norvasc* often looks like *Navane*® when handwritten. The pharmacist will then take the necessary steps to confirm the prescription if necessary.

In addition, physically separating drugs with look-alike labels and packaging helps to reduce this confirmation bias as does implementing bar-coding technology for the verification process of drug selection. Employing a simple system that compares computer-generated National Drug Codes (NDC) on prescription labels and NDC codes on manufacturers' containers to verify that the appropriate drug has been selected and dispensed also helps reduce confirmation bias.

It is human nature for people to associate items by certain characteristics. It is very important for the health care community and regulators to recognize the role that confirmation bias may play in medication errors and to work together to address associated problems.

FDA-TRACK Provides Public Access to Agency's Performance Data

The new FDA-TRACK will provide access to updated information about FDA programs, projects, and core responsibilities. The system is part of the FDA transparency initiative and its objectives are represented in the TRACK name which stands for transparency, results, accountability, credibility, and knowledge-sharing. This agency-wide system will track performance measurement data reported from over 100 FDA program offices. Common measures, key center director measures, program measures, and key projects are the measurement areas currently in use, and more information about these areas is available in the FDA-TRACK announcement available at www.fda.gov/AboutFDA/WhatWeDo/track/default.htm. FDA-TRACK will continue to be updated and the latest information can be found on the following Web pages: Cross-Agency FDA-TRACK Program Areas available at www.fda.gov/AboutFDA/WhatWeDo/track/ucm206441.htm, Center FDA-TRACK Program Areas available at www.fda.gov/AboutFDA/WhatWeDo/track/ucm206441.htm.



AboutFDA/WhatWeDo/track/ucm195008.htm, and Dashboards available at www.fda.gov/AboutFDA/WhatWeDo/track/ucm195011.htm. Public feedback on FDA-Track and its measures can be submitted by e-mail to FDATRACK@fda.hhs.gov.

Survey Suggests Majority of Patients Seek Pharmacist Advice About OTC Medications

When selecting OTC medications, 82% of pharmacy customers base their decision on a pharmacist's recommendation, according to a survey of over 1,000 pharmacists conducted by the American Pharmacists Association (APhA). Survey results also indicate which products, among 76 categories presented to pharmacists, are most often recommended. The survey results are published in the Pharmacy Today Over-the-Counter Supplement available at www.imirus.com/tmp/2536/2501/1001/pm2536.pdf. An APhA news release, available at www.pharmacist.com/AM/Template.cfm?Section=News_Releases2&Template=/CM/ContentDisplay.cfm&ContentID=23117, indicates that 90% of patients seek help identifying the most appropriate product and 80% seek counsel regarding using an OTC product with their prescription medications.

California PMP Data Shows Frequency of Doctor Shopping

Early data collected from California's prescription monitoring program (PMP), the Controlled Substances Utilization Review and Evaluation System (CURES), correlates the frequency of patient "doctor shopping," or obtaining multiple prescriptions from various providers, with the number of prescriptions patients receive for additional controlled substances, as reported in *Medical News Today*. The research analysis, presented at the American Academy of Pain Medicine 26th Annual Meeting, showed that patients prescribed a single additional class of a controlled substance, such as benzodiazepines, had a two-fold likelihood of doctor shopping for multiple opioid prescriptions. A 13-fold increase in doctor shopping was seen when more than one additional drug class was involved. Researchers at the University of California, Davis, conducted the analysis using de-identified CURES data, and also found that patients involved in doctor shopping were involved in more than one episode about 50% of the time.

Highest Dose of Zocor Increases Risk of Muscle Injury, FDA Warns

FDA has informed health care practitioners that there is an increased risk of muscle injury in patients taking the highest approved dose of the cholesterol-lowering medication, Zocor[®] (simvastatin) 80 mg. This information is based on review of data from a large clinical trial and other sources, and FDA is currently reviewing additional data to better understand the relationship between high-dose simvastatin use and muscle injury. More information is included in an FDA Drug Safety Communication at www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm204882.htm.

New OxyContin Formulation to Help Prevent Abuse of the Drug

FDA has approved a new formulation of the controlled-release drug OxyContin[®] which is designed to decrease the likelihood that this medication will be misused or abused, and result in overdose. FDA explains that the new formulation adds in new tamper-resistant features aimed at

preserving the controlled release of the active ingredient, oxycodone. The old formulation allowed tampering with the tablet, via cutting, chewing, breaking, or dissolving, which resulted in dangerously high levels of oxycodone being released at once. In accordance with FDA requirements, Purdue Pharma L.P. will conduct a post-marketing study to determine the impact of the new formulation, and the manufacturers will follow a Risk Evaluation and Mitigation Strategy (REMS) for this product. The REMS will include the issuance of a Medication Guide to all patients who use the product. More information is provided on the FDA OxyContin Question and Answer Web page at www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm207196.htm.

Use of e-Prescribing Grows Dramatically

The number of electronic prescriptions increased 181% from 2008 to 2009, according to the 2009 National Progress Report on E-Prescribing, published by Surescripts, operator of the largest e-prescription network that connects prescribers' e-prescribing software to pharmacies. Over 190 million e-prescriptions were routed in 2009, compared with 68 million in 2008, and 29 million in 2007. Correlating with those increases, 156,000 prescribers were using e-prescriptions by the end of 2009 compared with 74,000 at the end of 2008, a 109% increase. The report also indicates that 85% of community pharmacies in the United States are connected and able to receive e-prescriptions from prescribers.

Study Shows e-Prescribing Reduces Prescriber Errors

Prescribers using e-prescribing were seven times less likely to make errors than those writing their prescriptions by hand, according to a new study published in the *Journal of General Internal Medicine*. The study, conducted by researchers at Weill Cornell Medical College, focused on 12 community practices and compared the prescriptions of 15 providers using e-prescribing and 15 providers writing prescriptions by hand. The researchers found that two in five handwritten prescriptions contained errors such as incomplete directions, prescribing a medication but omitting the quantity, and prescribing incorrect dosages. Further, comparing handwritten prescriptions and e-prescriptions one year from the start of the study, researchers found that errors dropped from 42.5% to 6.6% for the providers using e-prescriptions. Errors associated with the handwritten prescriptions in the study increased from 37.3% to 38.4% a Weill Cornell Medical College press release providing more information about the study is available at http://weill.cornell.edu/news/releases/wcmc/wcmc_2010/02_26_10.shtml.

Counterfeit Drug Investigation Leads to Two Arrests

Two individuals have been arrested and face charges related to illegally importing counterfeit weight-loss medication. FDA issued a series of alerts, from 2008 to 2010, about tainted weight-loss pills and counterfeit drugs, and an undercover investigation identified one of the defendants as the alleged trafficker of these tainted and counterfeit drugs. This investigation was a joint effort by FDA Office of Criminal Investigations, US Immigration and Customs Enforcement, and US Postal Inspection Service. More information about the investigation and arrests is available in a US Attorney's Office Press Release at www.fda.gov/ICECI/CriminalInvestigations/ucm206314.htm.

ACTION: Notice; solicitation of information.

Summary: To analyze ongoing issues related to the dispensing of controlled substances to residents residing at long term care facilities (LTCFs), DEA is soliciting information on this subject from practitioners, pharmacists, LTCFs, nurses, residents and family of residents in long term care facilities, State regulatory agencies, and other interested members of the public. Specifically, DEA is exploring whether – while adhering to the framework of the Controlled Substances Act – any further revisions to the DEA regulations are feasible and warranted toward the goal of making it easier for residents of LTCFs to receive controlled substance medications. This notice recites the pertinent statutory considerations and contains a series of questions designed to elicit public comment that will assist DEA in making this evaluation.

As part of this request for comments, the *Federal Register* notice also outlines 56 questions to focus comments on. All comments are due to DEA on or before August 30, 2010. Please refer to the *Federal Register* notice for details on how comments may be sent to DEA on this issue.

Technician Permit Renewals

The Arkansas State Board of Pharmacy will be sending out pharmacy technician permit renewals in October. Pharmacy technicians need to ensure that they have filed their current mailing address with the Board office in order to receive their renewal reminders. These permit renewal reminders are sent directly to pharmacy technicians and it should be noted that technician permits that are not renewed will expire on December 31, 2010. The Arkansas State Board of Pharmacy allows a grace period until March 31, on permits. However, there is a \$20 penalty on technician permit renewal if not renewed by February 1, a \$40 penalty if not renewed before March 1, and if a permit is not renewed by April 1, then the permit is void. The Board strongly encourages you to use the Board's Web site to renew technician permits via the Internet, as it will speed up the renewal process for your technicians and it will also reduce the turn around time for technicians to receive their new permits. This is also the only way that the Board can accept credit card payments for renewal of these permits.

Business Permit Renewals

The following additional permits are also in their renewal cycle at this time: charitable clinic pharmacies, institutional pharmacies, wholesale distributors, List 1 chemical distributors, hospital pharmacies, nursing home consultants, and durable medical equipment permits. Charitable clinic permits and institutional permits cannot be renewed via the Internet, but all others may be renewed through the Board's Web site. Once again, renewing these permits via the Internet will allow use of a credit card for payment and will also greatly reduce the turn around time for delivery of the new permits.

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 at 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 – August 2010

The *Arkansas State Board of Pharmacy News* is published by the Arkansas State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, 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 the Foundation or the Board unless expressly so stated.

John Kirtley, PharmD - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor
& Executive Editor
Larissa Doucette - Communications Manager

Presorted Standard
U.S. Postage
PAID
Chicago, Illinois
Permit No. 5744

ARKANSAS STATE BOARD OF PHARMACY
National Association of Boards of Pharmacy Foundation, Inc
1600 Feehanville Drive
Mount Prospect, IL 60056