September 2010 News



# Kansas State Board of Pharmacy

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### Kansas' New Electronic Weapon in the War on Meth

For Kansas methamphetamine cooks, getting a key ingredient for making the illegal drug is about to get much more difficult. The Kansas State Board of Pharmacy adopted the Kansas Electronic Methamphetamine Precursor Logging (KEMPL) tracking system through rules and regulations on August 24, 2010. K.S.A. 65-16,102, which took effect on July 1, 2009, required the Kansas State Board of Pharmacy to establish and maintain a real time electronic logging system for use by all pharmacies in the state of Kansas that sell over-the-counter cold and allergy medications containing ephedrine, pseudoephedrine (PSE), and/or phenylpropanolamine products.

The move to electronic tracking was the result of the recommendation of the Kansas Methamphetamine Precursor Scheduling Task Force, which was formed in 2008 in response to the growth in illegal over-the-counter purchases of cold medicines for use in the manufacture of methamphetamine. The group recommended the state establish a real time electronic logbook system and require any pharmacy selling pseudoephedrine or ephedrine products to utilize the system.

The legislation required the Board to establish and provide the electronic system technology at no cost to the pharmacy. The legislature did not fund the project but they did permit the Board to contract with a private vendor and to accept donations, gifts, or grants for the funding of this project. The Board became aware of the National Precursor Log Exchange (NPLEx), which is a collaboration led by the National Association of Drug Diversion Investigators as well as law enforcement, health care professionals, state regulatory agencies, and pharmaceutical manufacturers. NPLEx is funded by manufacturers of those medicines and therefore is free of charge to any state that chooses to join the system.

The NPLEx system is connected to approximately one-third of the nation's pharmacies. Launched in Kentucky two years ago, NPLEx tracks the sale of more than 344,000 boxes of over-the-counter cold and allergy medicines per month in pharmacies across the country. Since the NPLEx database is multistate, illegal purchases are blocked across state lines, preventing methamphetamine cooks from obtaining the precursor of any other

NPLEx-connected retailer. NPLEx states include Louisiana, Missouri, Illinois, and Iowa. Kansas will become the next state to deploy the NPLEx system and Washington, Alabama, South Carolina, and Florida have passed legislation to move forward with electronic tracking and to join the NPLEx network.

The technology provider of the NPLEx system is Appriss, Inc, of Louisville, KY. The NPLEx system enables pharmacies to easily enter the same PSE sales data currently being gathered online rather than recording the information into a manual log or in-store computer system. Data will be stored in a secure, central repository that treats the data collected as if it were Health Insurance Portability and Accountability Act data. Furthermore, the collected data will be viewable by law enforcement, in keeping with Combat Methamphetamine Epidemic Act and SB 33. To secure your sales information, only your pharmacy will be able to inquire and view your sales data.

The Board is currently drafting an agreement to use the NPLEx system. Once the agreement has been approved each pharmacy will be contacted with more information related to integration, training, and other questions. Appriss will provide training sessions for all pharmacies located throughout the state and will provide follow-up IT support. If your pharmacy does not sell over-the-counter PSE products or your pharmacy only administers PSE products by prescription you can go through an exemption process that will also be detailed at a later date. The whole project should be completed and in place by December 17, 2010, in order to avoid the new year's insurance and Medicare changes. The Board looks forward to partnering with you on this important effort.

### Board of Pharmacy Moves to New Location

After more than 10 years of calling Landon State Office Building home, the Board of Pharmacy moved a block north to the corner of 8th and Jackson. The new address is 800 SW Jackson, Ste 1414, Topeka, KS 66612. After a brief office closure to accommodate the move, the Board of Pharmacy's operations resumed at the new location. The phone number remains the same at 785/296-4056 and the fax is 785/296-8420. The new location will allow the Board of Pharmacy to enhance its service to the citizens of Kansas and to provide ample space for the Prescription Drug Monitoring Program.

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## National Pharmacy

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### 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 <a href="https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingOver-the-CounterMedicines/ucm092139.htm">https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingOver-the-CounterMedicines/ucm092139.htm</a>.

### 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 <a href="www.ismp.org/Tools/confuseddrugnames.pdf">www.ismp.org/Tools/confuseddrugnames.pdf</a> 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 Norvasc® 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/

## Compliance News

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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 <a href="https://www.imirus.com/tmp/2536/2501/1001/pm2536.pdf">www.imirus.com/tmp/2536/2501/1001/pm2536.pdf</a>. An APhA news release, available at <a href="https://www.pharmacist.com/AM/Template.cfm?Section=News\_Releases2&Template=/CM/Content Display.cfm&ContentID=23117">www.pharmacist.com/AM/Template.cfm?Section=News\_Releases2&Template=/CM/Content Display.cfm&ContentID=23117</a>, 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 26<sup>th</sup> 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 <a href="https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm204882.htm">www.fda.gov/DrugSafetyInformationforPatientsandProviders/ucm204882.htm</a>.

### 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 <a href="https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsand">https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsand Providers/ucm207196.htm</a>.

### 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.

#### Immunization Statute Amended

The 2010 legislature amended K.S.A. 65-1635a related to immunizations. The change went into effect July 1, 2010. The Centers for Disease Control and Prevention have acknowledged that vaccination is the best protection against the flu. As part of the disease control strategy in Kansas, the Kansas Department of Health and Environment (KDHE) supported an amendment to the Pharmacy Act and testified in favor of this bill. KDHE felt that an increase in access to patients would decrease hospitalizations and deaths in Kansas. It would also minimize possible social and economic disruptions. They wanted to keep schools open, safe, and functioning. They promoted hygiene as well as encouraged workers and priority groups to get immunized against the flu.

In order to increase access to patients the legislature amended the statute so that a pharmacist or a pharmacy student or intern who is working under the direct supervision and control of a pharmacist may administer influenza vaccine to a person six years of age or older. They also amended the definition of pharmacist in K.S.A. 65-1626 to mean a pharmacist who has completed a course of study and training, approved by Accreditation Council for Pharmacy Education or the Board, in vaccination storage, protocols, injection technique, emergency procedures, and record keeping, and has taken a course in CPR and has a current CPR certificate. Another amendment to the immunization statute permits the pharmacist, pharmacy student, or intern to report the record of immunization to the vaccinee's primary-care provider by mail, electronic facsimile, e-mail, or other electronic means.

The Board of Pharmacy, KDHE, the Kansas Pharmacists Association, the Kansas Independent Pharmacy Services Corp, and the University of Kansas School of Pharmacy worked together to accomplish this amendment. It will benefit the citizens of Kansas by providing affordable access for immunizations against influenza.

Immunization certificates need to be maintained at the pharmacy where the pharmacist or student is working so that an inspector can view them.

#### Technician Permit Renewals

The Kansas State Board of Pharmacy will be sending out pharmacy technician permit renewal reminders in September. Pharmacy technicians need to ensure that they have filed their current home address with the Board office in order to receive their renewal reminders. The permit renewal reminders are sent directly to pharmacy technicians at their home address and it should be noted that technician permits that are not renewed will expire on October 30, 2010. The Kansas State Board of Pharmacy allows a 30-day grace period on permits. However, there is a \$25 penalty on technician permit renewals if not renewed before December 1. The Board strongly encourages you to use the Board's Web site to renew technician permits via the Internet. This is the only way that the Board can accept credit cards. The Web renewal system will also accept checks as a form of payment.

### Tech Check Tech in a Medical Facility

The Board amended K.A.R. 68-7-11 related to a technician checking the work of another technician in the hospital setting. This practice had previously been permitted in certain hospitals

that obtained permission from the Board. The Board wanted to expand the practice to any hospital that wanted to use this system so long as they followed specific guidelines. Except with regard to drugs that have not been checked for accuracy by a pharmacist after having been repackaged, prepackaged, or compounded in a medical care facility pharmacy, a pharmacy technician in a medical care facility may check the work of another pharmacy technician in filled floor stock, a crash cart tray, a unit-dose cart, or an automated dispensing machine if the checking pharmacy technician meets each of the following criteria:

- Has a current certification issued by the Pharmacy Technician Certification Board or a current certification issued by any other pharmacy technician certification organization approved by the Board. Any pharmacy technician certification organization may be approved by the Board if the Board determines that the organization has a standard for pharmacy technician certification and recertification not below that of the Pharmacy Technician Certification Board.
- 2. Has either of the following experience levels:
  - (A) one year of experience working as a pharmacy technician plus at least six months experience working in the medical care facility at which the checking will be performed; or
  - (B) one year of experience working as a pharmacy technician in the medical care facility at which the checking will be performed.
- Has successfully completed a written training program and related examination designed by the pharmacist-in-charge of the medical care facility pharmacy to demonstrate competency in accurately checking whether floor stock, a crash cart tray, and an automated dispensing machine have been properly filled.

### Disciplinary Cases

**Diane Wasinger**, Pharmacist License Number 1-11386: Revocation of licensed based on revocation of license out of the state of Missouri

### Continuous Quality Improvement Records

This is a reminder that each pharmacy should have a continuous quality improvement (CQI) meeting in September. Inspectors will be checking to make sure that a CQI meeting was held and that all incident reports were reviewed. If you have any questions regarding CQI reporting contact your Board inspector or the Board office.

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