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Kansas State Board of Pharmacy News

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Coming Soon – Kansas Drug Disposal Program

The Kansas State Board of Pharmacy is drafting a policy that would permit a pharmacy to accept unwanted **non-controlled** drugs by ultimate users for drug disposal. This would help facilitate the collection and destruction of household medications that can easily be in the reach of children or teenagers. The Board has been working toward ensuring that expired or unused medications can be destroyed safely and in an affordable way. A lot of care also needs to be taken so that there will be no adverse impact on the ecosystem.

The Board has been working with the Kansas Department of Health and Environment (KDHE) to develop a program that complies with all federal and state law. Currently, the only option in which a pharmacy can accept returns is through the Drug Enforcement Administration's (DEA) National Take-Back Initiative. KDHE has taken the first step by changing its policy so that dispensed drugs can be classified as household waste rather than hazardous waste. The Board is working with KDHE to develop a program that provides appropriate pharmaceutical safeguards and security as well as using an environmentally friendly method. The Board is also looking at providing a cost effective alternative since this will be a volunteer program.

The program will not be able to dispose of the most dangerous pharmaceutical drugs, controlled substances. DEA is working on federal regulations taking into account Public Law 111-273, the Secure and Responsible Drug Disposal Act of 2010. However, until their regulations are in place the Board of Pharmacy and KDHE will develop policies on the safe disposal of non-controlled drugs in Kansas.

K-TRACS Threshold Letters

Many of you may have received a "threshold letter" from the Board of Pharmacy's Kansas Tracking and Reporting of Controlled Substances (K-TRACS) program related to a specific patient and you may be unsure of what to do with the information. K-TRACS runs queries on patients who have gone to multiple providers and often multiple dispensers during a specific period of time. The information may not provide you with enough information to make a judgment about whether the patient exhibits risks of drug abuse, but the information can be used as a tool. You are not required by law to access or use the information, but it can improve your knowledge about the patient.

Pharmacists are often the most accessible health care professional to the patient. It can put pharmacy in the front line when dealing with patient issues related to substance abuse and chemical dependence. Even the most seasoned health care provider may have difficulty determining how to deal with K-TRACS information. In order to determine whether there is a problem a pharmacist should acquire a complete drug history of all patients in his or her care. This will require asking the patient about his or her drug usage. A drug history should be conducted in as confidential an atmosphere as possible and the patient should be assured that the information they provide is confidential.

Many of the pharmacists have reported they are experiencing patients who have increased stress and anxiety over the pharmacy's access to K-TRACS. If you detect the patient beginning to get angry, respond calmly and treat the patient with respect. You can share information you have with the patient but you **cannot** give the patient a copy of the K-TRACS report. You can express concern for the patient and try to understand his or her problem. Regardless of the extent of the patient's anger, document any complaint the patient has as well as any attempts you made to resolve the situation. It is not a violation if the pharmacist uses his or her professional judgment and refuses to fill a prescription. If the patient complains to the Board you may be asked for specific details of the event so that the Board can adequately address the patient's complaint with the patient. The Board of Pharmacy has a brochure titled "K-TRACS – How K-TRACS Helps Fight Against Prescription Drug Abuse." If you would like brochures to have available for your patients contact K-TRACS staff at the Board office at 785/296-6547 and they will provide them to you. It contains information for the public along with many resources that are available.

It is your decision whether or not to decline to fill a prescription. Firing a patient based solely on a K-TRACS report may not be in the best interest of the patient. Not every patient who sees multiple doctors is a drug seeker. Each case should be examined on its own merits and you will have to use your own

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FDA Recommends Use of Sterile Needle and Syringe for Administration of Inactivated Influenza Vaccines

Food and Drug Administration (FDA) recommends that health care providers use a sterile needle and syringe to administer inactivated influenza vaccines. The recommendation was released in response to questions regarding the use of jet injector devices to administer inactivated influenza vaccines. FDA advises that "inactivated influenza vaccines that are approved by FDA have information in their labeling stating how the vaccines should be administered, such as, by intramuscular (IM) or intradermal (ID) administration." Further, FDA clarifies its October 21, 2011 communication "to inform the public that inactivated influenza vaccines labeled for IM injection are intended for administration using a sterile needle and syringe. There is one inactivated influenza vaccine labeled for ID administration, this vaccine is supplied in its own pre-filled syringe. The live attenuated influenza vaccine is given through the nose as a spray; the sprayer is not a jet injector." FDA also notes the following:

- Currently, there is only one vaccine, Measles, Mumps, and Rubella (MMR), that is approved and specifically labeled for administration by jet injector.
- Safety and effectiveness information that would support labeling inactivated influenza vaccines for delivery by jet injector have not been submitted to FDA.
- At this time, there are no inactivated influenza vaccines that are approved and specifically labeled by FDA for administration by jet injector.

FDA recommends that all approved vaccines, including influenza, be administered in accordance with their approved labeling, and FDA advises that if a vaccine has been approved for administration with a jet injector, information specifically addressing vaccine use with a jet injector will appear in the vaccine labeling. Additional background information is available in the communication posted on the FDA Web site at *www.fda.gov/BiologicsBloodVaccines/Vaccines/QuestionsaboutVaccines/ucm276773.htm.*

The Centers for Disease Control and Prevention continues to encourage people to get vaccinated throughout the flu season, which can begin as early as October and last as late as May. For information about the flu vaccine visit *www.cdc.gov/flu.*

'Tell Back' Works Best to Confirm Patient Understanding

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 an 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.*

In the past few years, multiple studies have demonstrated that patients often leave medical encounters with a poor understanding of their health conditions and recommended treatment. One recent study on this subject demonstrates the low level of understanding patients have about follow-up care and medication therapy upon discharge from the emergency department (Engel KG et al. Patient Comprehension of Emergency Department Care and Instructions: Are Patients Aware of When They Do Not Understand? Ann Emerg Med. Available on the journal Web site).

Given the importance of patient understanding of medical information, there are surprisingly few studies that point out how to approach this task. However, a study published in 2008 offers some insight into what approach to assessing understanding of medical information patients most prefer and perceive to be the most effective (Kemp EC, et al. Patients Prefer the Method of "Tell Back-Collaborative Inquiry" to Assess Understanding of Medical Information. J Am Board Fam Med 2008;21(1):24-30). Researchers tested three types of inquiry about the patient's understanding:

- Yes-No
- Tell Back-Directive
- Tell Back-Collaborative

The Yes-No approach asked closed-ended questions to assess patient understanding. (Example: "I've given you a lot of information. Do you understand?") The Tell Back-Directive method used open-ended questions that were physician-centered and paternalistic in that it was clear authority and control still remained with the physician. (Example: "It's really important that you do this exactly the way I explained. What do you understand?") The Tell Back-Collaborative approach used open-ended questions that were patient centered, making it clear that power and responsibility were shared between the health care provider and patient. (Example: I imagine you are really worried about your blood pressure. I've given you a lot of information. It would be helpful to me to hear your understanding about your clot and its treatment.)

Patients showed a significant preference for the Tell Back-Collaborative inquiry over other tested approaches. Because of the potential for embarrassment if patient misunderstandings are exposed, one might anticipate health care providers' reluctance to put patients "on the spot" with open-ended questions. But a collaborative approach to Tell Back allows the patient to save face for misunderstandings by acknowledging the large amount of information being provided. Patients might also view the request for Tell Back as evidence of the health care provider's care and concern for them personally, or evidence of the provider's attention to detail and competence. So, when counseling patients about their medications, instead of asking "Do you have any questions?" or "Do you understand?" ask them to restate their understanding of the information you provided in their own words within a shame-free, blame-free environment.

DEA Clarifications on Certification Process for Audits of EPCS Software

Drug Enforcement Administration (DEA) emphasizes that third-party audits of software applications for Electronic Prescriptions for Controlled Substances (EPCS) must encompass all applicable requirements in DEA regulations, including security, and must address "processing integrity" as set forth in the regulations. Further, DEA recommends that where questions or gaps may arise in reviewing a particular applica-

tion, federal guidelines set forth in National Institute of Standards and Technology Special Publication 800 – 53A should be consulted. DEA has also announced the first DEA-approved certification process for EPCS. Certifying organizations with a certification process approved by DEA pursuant to the regulations are posted on DEA's Web site at *www.deadiversion.usdoj.gov/ecomm/e_rx/thirdparty.htm#approved*. Detailed background information is provided in the Federal Register Notice, available for download at *www.gpo.gov/fdsys/pkg/FR-2011-10-19/pdf/2011-26738.pdf*.

'Script Your Future' Provides Tools and Outreach to Encourage Medication Adherence

United States Surgeon General Regina Benjamin called upon pharmacists, physicians, nurses, and other health care providers to talk with their patients about the importance of taking medications as directed to help prevent serious health complications at the recent launch of the national campaign, "Script Your Future." Benjamin also "encouraged patients with chronic conditions to speak with their health care professionals about their medication" as noted in a press release. A survey released by the National Consumer League, the organization that developed Script Your Future, indicates that "patients who do not always take their medication as directed are less likely to have received a full explanation of the consequences of their condition, and are less convinced of the importance of adherence." The Script Your Future campaign is targeting six regional areas with outreach activities and advertising, and more information is available at *www.ScriptYourFuture.org*. The campaign brings together "stakeholders in health care, business, and government to offer practical tools for patients to help them better adhere to their medication, and to help health care professionals better communicate with patients." More information about the campaign is available in a press release at *www.prnewswire.com/news-releases/us-surgeon-general-joins-baltimore-launch-of-the-national-script-your-future-campaign-to-highlight-importance-of-taking-medication-as-directed-133077423.html*.

FDA Releases 'Use Medicines Wisely' Video

FDA Office of Women's Health has released a new public service announcement (PSA) video titled, "Use Medicines Wisely," to help raise awareness about safe medication use. As stated in an FDA news release, "Millions of people benefit from FDA approved medications and are living longer productive lives. However, when medications are used incorrectly, they can cause serious injuries, even death. Many of these injuries can be prevented."

The video shows simple steps women can take to use medications wisely. Viewers are reminded to:

- Make a list of the medications they take
- Keep their medication list with them at all times
- Know the name of each medication, why they are taking it, how much to take, and when to take it
- Talk with their doctor, nurse, or pharmacist to find out how to safely use their medications

In addition to the video, a medications record-keeper, fact sheets, and other safe medication use resources are available on the FDA Web site.

Training Video Provides Tips on Preventing Pharmacy Robbery

Rx Pattern Analysis Tracking Robberies and Other Losses (RxPATROL) has released a training video discussing pharmacy robbery and how to prevent it. The video features a pharmacist and law enforcement liaison as they tour a pharmacy, evaluating security measures and discussing additional steps that can be taken to prevent robbery. RxPATROL is an initiative designed to collect, collate, analyze, and disseminate pharmacy theft intelligence to law enforcement throughout the nation. RxPATROL is designed to gather and disseminate critical information to help protect pharmacists, guard against potential robberies, and assist law enforcement in their efforts to successfully apprehend and prosecute those involved in controlled substance pharmacy crime. The training video can be accessed on the RxPATROL Web site at *http://rxpatrol.org/TrainingVideos.aspx*.

Nearly 20 Products Marketed as Natural Supplements Contain Sibutramine, FDA Warns

FDA has posted public warnings regarding 19 products, frequently marketed as natural supplements, and found to contain sibutramine, a controlled substance that was removed from the US market in October 2010 for safety reasons. These products pose a threat to consumers because sibutramine is known to substantially increase blood pressure and/or pulse rate in some patients and may present a significant risk for patients with a history of coronary artery disease, congestive heart failure, arrhythmias, or stroke. These products may also interact in life threatening ways with other medications a consumer may be taking. FDA warnings included products marketed as "Slender Slim 11," "Dream Body Slimming Capsule," "Acai Berry Soft Gel ABC," and 16 other product names. The products included in the warnings are being sold on Web sites and in some retail stores. FDA advises consumers not to purchase or use the products listed in the warnings. Consumers who have purchased any of these products should stop use immediately. And if consumers have experienced any negative side effects from using these products, they should consult a health care provider as soon as possible. The complete list of warnings is available on the FDA Web site at *www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm234592.htm*.

2012 Survey of Pharmacy Law Now Available

Serving as a convenient reference source for individuals seeking an overview of the state laws and regulations that govern pharmacy practice, the updated 2012 *Survey of Pharmacy Law* is now available and can be purchased online for $195 by visiting the NABP Web site at *www.nabp.net/publications*.

The *Survey,* produced in a CD format, consists of four sections including a state-by-state overview of organizational law, licensing law, drug law, and census data. Newly added this year, a question in Section 17, Wholesale Distributor Licensure Requirements, asks which state agency has regulatory authority over medical device distributors. In addition, a newly added question in Section 22, Electronic Transmission of Prescriptions: Computer-to-Computer, asks whether the state allows electronic prescribing of controlled substances.

Updates for the 2012 *Survey* were graciously provided by the state boards of pharmacy. In addition to the boards' support, NABP requested data from relevant health care associations for the *Survey's* prescribing authority and dispensing authority laws in Sections 24 and 25, and laws pertaining to the possession of non-controlled legend drugs and possession of controlled substances in Sections 26 and 27.

All final-year pharmacy students receive the *Survey* free of charge through the generous grant of Purdue Pharma L.P.

For more information on the *Survey,* please contact Customer Service via phone at 847/391-4406 or via e-mail at custserv@nabp.net.

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judgment. The Board recommends that you contact the prescriber and work as a team in order to treat the patient. When you speak to the practitioner you can share the information from the K-TRACS report but you **cannot** make a copy for the doctor. The doctor would need to access the report from K-TRACS and make his or her own copy.

Develop a list of local resources for drug abuse treatment. Not only is it helpful to assess drug dependency but you may want to refer individuals and collaborate with physicians caring for chemically dependent patients. You may also refer the patient to a Kansas Department of Social and Rehabilitation Services ValueOptions treatment provider, toll-free at 866/645-8216.

A pharmacist is permitted to contact law enforcement if concerned about a patient violating drug laws. You can give information to a law enforcement officer but you **cannot** make a copy of the K-TRACS report. If your law enforcement agency tells you that they need access to the report ask them to contact the K-TRACS director, Christina Morris, at the Board office and she can tell them how they can get access to the information.

The Board understands the predicament that K-TRACS can put the pharmacist in when dealing with an angry patient. The Board does expect you to treat each patient with respect even if the patient behaves in a way that is not generally acceptable. How one responds to an angry or abusive patient involves listening, empathy, respect for others, and using assertive communication.

Disciplinary Cases

Jeremy Cortez (14-08091). Case No. 10-85. Pharmacy technician registration revoked for drug diversion from employer.

Lance Ray Norris (1-10541). Case No. 11-38. Suspension of pharmacist license for drug diversion from employer.

Katherine Surowski (1-13879). Case No. 11-79. Pharmacist license revoked for conviction of conspiracy to distribute/dispense controlled substances and health care fraud.

Kaesha Sanders (14-09245). Case No. 11-82. Pharmacy technician revocation for drug diversion from employer.

Got Drugs? National Take-Back Initiative

DEA has scheduled another National Prescription Drug Take-Back Day on Saturday, April 28, 2012, from 10 AM to 2 PM, to provide a venue for persons who want to dispose of unwanted and unused prescription drugs.

According to DEA, Americans who participated in the drug take-back day on October 29, 2011, turned in more than 377,086 pounds (188.5 tons) of unwanted or expired medications for safe and proper disposal. For more information on how to participate in your community visit the DEA Web site at *www.deadiversion.usdoj.gov/drug_disposal/takeback/index.html.*

National Association of State Controlled Substance Authorities

Christina Morris, JD, the Kansas Prescription Drug Monitoring Program director was recently elected to the Executive Committee of the National Association of State Controlled Substance Authorities (NASCSA). NASCSA is a non-profit educational organization established to provide a continuing mechanism through which state and federal agencies work to increase the effectiveness and efficiency of state and national efforts to prevent and control drug diversion and abuse. Christina will also serve on the Policy and Procedure Committee, the Resolutions and By-laws Committee, and the Membership Committee. Congratulations, Christina.

Carisoprodol (Soma) a Schedule IV Drug

Effective January 11, 2012, carisoprodol (Soma®) was placed on the Schedule IV controlled substance list. DEA has provided guidance on how to provide fills and refills for prescriptions that were written before January 11, 2012. Licensees may continue to dispense these prescriptions if the prescription was written by an authorized DEA registrant with a DEA number. If the prescriber does not have a DEA number, those prescriptions should be canceled and not dispensed. The prescription may not be filled or refilled more than six months after the date the prescription was issued. Therefore, if a prescription for a drug containing carisoprodol was issued before January 11, 2012, and refills were authorized, as of January 11, 2012, those refills (no more than five) must be dispensed no later than six months after the date the prescription was issued. Further information can be found on the DEA Web site at *www.deadiversion.usdoj.gov/drugs_concern/carisoprodol/index.html.*

Serve on the Board of Pharmacy

To submit an application to serve on a board or commission such as the Board of Pharmacy contact Governor Sam Brownback's office. An application may be filled out on the Governor's Web page at *https://governor.ks.gov/contact-the-governor.* Once the form is completed you can mail it or fax it to the Governor's Office of Appointments with your résumé and completed Statement of Substantial Interest. The Statement of Substantial Interest can be located on the Secretary of State Web site at *www.kssos.org/elections/ssi_online.asp.* The appointments secretary is Kim Borchers and her address is Capitol Building, 300 SW 10th Avenue, Room 259-S, Topeka, KS 66612-1590. You might also let your legislators know if you are interested in serving on the Board of Pharmacy. The requirements for Board membership are that you are a resident of Kansas and are actively employed or engaged in the practice of pharmacy for at least five years preceding the appointment date. The Board is required to meet at a minimum four times a year and the meetings generally last a day and a half. Other commitments may include serving on committees or attending national meetings. The Board tackles challenging issues involving compliance, protection of the public health, safety and welfare, as well as provides education to the community and licensees. The Board of Pharmacy needs talented individuals who subscribe to the ideal that pharmacy practice is a public trust and that the Board will assure a balanced and sensible approach to regulation.

The *Kansas State Board of Pharmacy News* is published by the Kansas 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.

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