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Kansas State Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

New Regulations

On November 13, 2009, an amendment to K.A.R. 68-20-16 related to controlled substance inventories became effective. The regulation will now require an inventory of all controlled substances to be done every year. Every person is required to take an initial inventory of all stocks of controlled substances on the date he or she first engages in the dispensing of controlled substances. After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand every year. If the substance is listed in Schedule I, II, or contains hydrocodone, an exact count or measure of the contents shall be recorded. If the substance is listed in Schedule III, IV, or V and does not contain hydrocodone, an estimated count or measure of the contents must be taken, unless the container holds more than 1,000 tablets or capsules in which an exact count must be taken. This regulation is stricter than federal law which requires a biennial inventory. The inventory may be taken at the opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory. Each inventory should be signed and dated. Inventory records shall be maintained a minimum of five years in the pharmacy.

On October 23, 2009, several amendments to regulations became effective. One amendment was made to K.A.R. 68-2-22 related to electronic prescription transmissions. If a prescription or drug order is communicated by an electronic transmission it needs to be maintained as either a hard copy or an electronic document. Therefore, a phoned in and faxed in prescription must be maintained for a minimum of five years as either a hard copy or an electronic document. If the copy is maintained as an electronic document it must be retrievable and available to the pharmacy inspector if requested.

K.A.R. 68-1-1h is related to foreign pharmacists. A pharmacist who graduated from a school outside the United States or who is not a citizen of the United States has to provide proof that they are proficient in English. In addition to taking an English language test the individual must take and pass the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) with a score of at least 75. When the graduate has successfully passed the FPGEE and the English proficiency test they will be given a Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) certificate, which must be submitted to the Kansas State Board of Pharmacy. This regulation clarified the foreign pharmacist requirements.

K.A.R. 68-1-3a clarified qualifying pharmaceutical experience requirements of interns. Each intern must obtain 1,500 clock hours as a pharmacy student or intern while being supervised by a preceptor. The preceptor may supervise no more than two individuals at any one time. The intern may not receive more than 60 hours during any one week. The intern may not obtain hours prior to being accepted in an approved school of pharmacy and he or she may not obtain intern hours prior to being registered with the Board of Pharmacy. Foreign pharmacy graduates who have obtained their FPGEC certificate may apply for registration as an intern. Once an intern is registered he or she must complete 1,500 hours within six years. Pharmacists who are applying for licensure by transferring from another state will not be denied a license in Kansas if they have met the internship requirements of the state from which they are reciprocating and have at least one year of experience as a pharmacist.

The last change that was effective on October 23, 2009, was the amendment made to K.A.R. 68-7-14 regarding prescription labels. The only change that was made to this regulation was that the label for each drug or device shall include the name of the prescriber. The prescription label no longer requires the name of the mid-level practitioner and the supervising physician to be on the label. The label may still have both the name of the physician and

Continued on page 4

Pharmacy Security and Safety Prove Necessary Component in Pharmacists' Training

Pharmacy robbery – no one ever thinks it will happen to them, but those who have experienced it know it **can** happen to anyone. To address the importance of recognizing actions to follow if faced with a robbery, several boards of pharmacy have included pharmacy safety resources in their state newsletters and on their Web sites. In addition, to keep current licensees aware and up to speed on safety measures, procedures can be directly taught and reiterated in the pharmacy. Likewise, at least one college of pharmacy has begun incorporating pharmacy safety training in its curriculum and recently saw the extreme benefits of doing so.

On Wednesday, July 8, 2009, Dustin Bryan, a P2 doctor of pharmacy candidate at Campbell University College of Pharmacy and Health Sciences, quickly learned how imperative pharmacy safety training really was when he experienced a pharmacy robbery first hand. Just as Bryan and his fellow employees were preparing to close the store, two gunmen entered the North Carolina pharmacy and approached the counter demanding OxyContin®. They left with bags filled with OxyContin and Percocet®, having a retail value of nearly $10,000.

Luckily, all employees involved remained unharmed and despite the situation, Bryan was able to remain calm, focusing on lessons he recently learned during his pharmacy management course at Campbell.

Bryan shared his experience in the university's college of pharmacy alumni e-Newsletter. In the article Bryan states, "I crouched down hoping they hadn't seen me so I could get to a safe place in an office behind the pharmacy to call the police. They saw me as I was crawling and made me come to the front of the pharmacy. My mind was running through a class Dr Cisneros taught dealing with a robbery," he explains. "I knew what type of questions the police would be asking from our lecture, and I was asking myself those very questions while the robbery was happening. It was a very intense and scary moment . . . but I am thankful for the class I had and that nobody was hurt during the whole ordeal."

In December 2008, a safety DVD, *Pharmacy Security – Robbery*, accompanied the shipments of the National Association of Boards of Pharmacy® *2009 Survey of Pharmacy Law* that were sent to the schools and colleges of pharmacy. The DVD was an educational offering from Purdue Pharma L.P. provided to the schools as part of an initiative to promote pharmacy safety education. Endorsed by National Association of Drug Diversion Investigators, Federal Bureau of Investigation Law Enforcement Executive Development Association, and National Community Pharmacists Association, the 15-minute video contains information that may be critical to preparing pharmacists in the event that they are faced with a robbery.

It was this DVD that Robert Cisneros, PhD, assistant professor at the university, implemented in his pharmacy management course – the very same course that helped Bryan stay calm during the robbery. Cisneros went a step further by arranging for the head of campus security to speak during the course.

"One of the biggest values of the DVD was pointing out things to focus on during a robbery such as the robber's appearance – clothes, height, weight – and not just focusing on the gun," states Cisneros. He was glad to have received the DVD, explaining that, "it was just the right length, added a lot to the class, and led to great discussions." Cisneros went on to share that he was surprised to learn only 50% of the students in his class this past spring had some form of training on what to do if robbed, though this was a significant increase from the less than 5% who indicated so a few years prior.

Pharmacy robberies may not be avoidable; however, with the proper knowledge, individuals faced with these frightening situations may be better prepared to avoid harm and to assist law enforcement officials in catching criminals before additional robberies occur.

The safety DVD mentioned above may be viewed on the RxPatrol® Web site at *www.rxpatrol.org*. RxPatrol is a collaborative effort between industry and law enforcement designed to collect, collate, analyze, and disseminate pharmacy theft information. The safety DVD, along with a variety of other non-branded educational materials, is also available through the Purdue Pharma Medical Education Resource Catalog, accessible at *www.partnersagainstpain.com* under Pain Education Center.

Concerns with Patients' Use of More than One Pharmacy

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.*

Perhaps it is not readily apparent, but medication safety could be compromised if patients practice polypharmacy to take advantage of widely publicized programs offering discounted or free medications. With tough economic times, patients may choose to fill or refill their prescriptions at multiple pharmacy

locations to save money, since taking advantage of such offers may cost less than filling their prescription at their usual pharmacy and paying the insurance co-pay.

Normally, when a customer presents a prescription, the pharmacy sends information about the drug and the patient to third-party payers and/or the patient's pharmacy benefit managers (PBM) for reimbursement.

If patients are paying out of pocket for the prescription, the pharmacy can notify the PBM so the medication can be tracked, but notification is not required. In these circumstances, the PBM and insurer may not be made aware that the prescription has been dispensed and no adjudication or drug utilization clinical screening of the prescription will be performed. Normally, medications are screened by the PBM's computer system, which includes all prescription medications regardless of where they were dispensed, and dispensing pharmacists are alerted to drug duplications, drug interactions, and some other unsafe conditions. This checking process will not occur if the prescription is not sent to the PBM. This also has an impact on hospitals that use outside vendors that obtain PBM data through Surescripts in order to populate patient medication profiles upon admissions to the emergency department or hospital. This could decrease the accuracy of drug lists collected for medication reconciliation since these vendors access their information from PBMs and insurers.

For these reasons, patients need to be educated about the importance of sharing insurance information wherever they have their prescriptions filled, even when the insurance is not being billed. Community pharmacists can help by submitting claims to insurance carriers, as cash, to keep an accurate medication profile for the patient. This is especially necessary if the patient is only filling a prescription for a drug on the $4 list from your pharmacy, but you suspect they may be taking other medications and obtaining them elsewhere. It is also important to expand our efforts to encourage patients to keep a complete list of medications, herbals, nutritional supplements, vitamins, and prescription drugs and to show this list to every provider of care they visit. Community pharmacies can also update patient medication profiles in their computer systems to include prescription and over-the-counter medications obtained at other pharmacies, including mail-order, and promoting and providing a written copy of this list to the patient upon request.

CDC Launches Get Smart Web Site to Help Decrease Antibiotic Resistance

Centers for Disease Control and Prevention (CDC) launched the Get Smart Web site to teach about the potential danger of antibiotic resistance and what can be done to prevent it. Because antibiotic resistance is one of the world's most pressing public health problems, CDC also held Get Smart Week on October 5-11 to emphasize its public health effort to decrease antibiotic resistance, including how pharmacists can become involved.

The Web site contains patient education materials, updated guidelines for health care providers, campaign materials, and additional resources, including information in Spanish, to help increase the public health awareness of antibiotic resistance and the importance of obtaining influenza vaccines in time for the upcoming flu season. As most states now allow pharmacists to immunize, they can help contribute to public health awareness on who should get flu shots and appropriate antibiotic use in the community. The Get Smart Web site can be accessed at *www.cdc.gov/getsmart/*.

FDA Approves Vaccine for 2009-2010 Seasonal Influenza and H1N1

Food and Drug Administration (FDA) has approved a vaccine for 2009-2010 seasonal influenza in the United States. FDA has also approved four vaccines against the 2009 H1N1 influenza virus. The seasonal influenza vaccine will not protect against the 2009 H1N1 influenza virus. More information is available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements*.

ISMP: Do Not Store Insulin Vials in Open Cartons – Risk of Mix-up High

ISMP warns that storing insulin vials inside their cardboard cartons after the packages have been opened can lead to mix-ups, and potential medical emergencies, if vials are accidentally returned to the wrong carton after being used. The next patient care worker looking for a particular insulin product could read the label on the carton, assume that it accurately reflects what is inside, and end up administering the wrong product. To avoid such a mishap, ISMP recommends that the cartons be discarded, either in the pharmacy before the insulin is dispensed, or when it is received at the nursing station.

FDA Takes Actions on Pain Medications Containing Propoxyphene

FDA announced in July that it will require manufacturers of propoxyphene-containing products to strengthen the label, including the boxed warning, emphasizing the potential for overdose when using these products. FDA will also require manufacturers to provide a medication guide for patients stressing the importance of using the drugs as directed. In addition, FDA is requiring a new safety study assessing unanswered questions about the effects of propoxyphene on the heart at higher than recommended doses. Findings from this study, as well as other data, could lead to additional regulatory action. In its July 7 denial of a citizen petition requesting a phased withdrawal of propoxyphene, FDA said that, despite "serious concerns . . . , the benefits of using the medication for pain relief at recommended doses outweighs the safety risks at this time." Additional information can be found at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm170769.htm*.

Continued from page 1

the physician assistant (PA)/advanced registered nurse practitioner (ARNP) or the label may only indicate the PA/ARNP's name followed by the proper designation. The actual prescription still requires the name of the mid-level practitioner and his or her supervising physician on the prescription. These are Kansas State Board of Healing Arts and Kansas State Board of Nursing requirements that the Board of Pharmacy has no jurisdiction over. A prescription is not valid if it does not contain the name of the mid-level practitioner who prescribed the drug, and the supervising practitioner.

These changes can all be found on the Board of Pharmacy Web page at *www.kansas.gov/pharmacy* under Kansas Pharmacy & Related Laws, under the link for Newly Approved Regulations with the title "New Regulations."

Long Term Care Facility DEA Changes

Drug Enforcement Administration (DEA) recently clarified what individuals have been authorized to call in a prescription order for a long term care facility (LTCF). DEA has recently interpreted its law strictly and determined that a nurse employed by a LTCF is not the agent of a physician. DEA has stepped up its enforcement in other states so the Board would caution pharmacies that they need to make sure that the prescriber has signed the medication order and contains all of the elements required on a prescription. The Board has provided frequently asked questions related to LTCFs on its Web site at *www.kansas.gov/pharmacy*.

Changes to a Schedule II Prescription

DEA has recently changed its position related to what changes can be made to a Schedule II prescription. The strict view is that no changes may be made to a Schedule II prescription regardless of whether the pharmacist verifies with the prescriber and documents the change. The DEA Office of Diversion Control Web site now states the following:

> **"What changes may a pharmacist make to a prescription written for a controlled substance in schedule II?**
>
> On November 19, 2007, the DEA published in the Federal Register (FR) the Final Rule entitled *Issuance of Multiple Prescriptions for Schedule II Controlled Substances* (72 FR 64921). In the preamble to that Rule, DEA stated that "the essential elements of the [schedule II] prescription written by the practitioner (such as the name of the controlled substance, strength, dosage form, and quantity prescribed) . . . may not be modified orally."

Disciplinary Cases

John Ingraham, Pharmacy Technician, Registration 14-05471: Registration Revoked. Mr Ingraham's technician registration was revoked for diversion of controlled substances (fentanyl, morphine, dextroamphetamine, Endocet®, Focalin®, hydromorphone, Metadate®, oxycodone, OxyContin®, Percocet®, Ritalin®, diazepam, Provigil®) from his employer.

Sheryl Martinson, Pharmacy Technician, Registration 14-01712: Registration Revoked. Ms Martinson's technician registration was revoked for diversion of controlled substances (hydrocodone) from her employer.

Penny Bishop, Pharmacy Technician, Registration 14-00619: Registration Revoked. Ms Bishop's technician registration was revoked for diversion of controlled substances (hydrocodone) from her employer.

Mary Ann Harper, Pharmacy Technician, Registration 14-00809: Registration Revoked. Ms Harper's technician registration was revoked for diversion of controlled substances (hydrocodone, hydromorphone, oxycodone) from her employer.

Crystal Crawford, Pharmacy Technician, Registration 14-07666: Registration Revoked. Ms Crawford's technician registration was revoked for diversion of controlled substances (hydrocodone) from her employer.

Brandy Holderby, Pharmacy Technician, Registration 14-07605: Registration Revoked. Ms Holderby's technician registration was revoked for diversion of controlled substances (hydrocodone, oxycodone, OxyContin) from her employer.

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 voluntary 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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