



Kansas State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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Fifty Years of Service

Congratulations to the following pharmacists who were honored in 2009 for completing 50 years of continuous licensed service to the citizens of Kansas and the profession of pharmacy. The Kansas State Board of Pharmacy is grateful for their years of contribution to the profession.

Richard K. Wade, RPh..... Fontana, KS
 Darrell L. Thorsell, RPh..... Meade, KS
 Sherwin Snyder, RPh..... Wichita, KS
 Frank W. Levell, Jr, RPh..... Kansas City, KS
 Allen R. Hale, RPh.....Wichita, KS
 James L. Enyart, RPh..... Shell Knob, MO
 James L. Disque, RPh.....New Providence, NJ
 William C. Daugherty II, RPh..... Lakin, KS
 William L. Cummings, RPh..... Wichita, KS
 Burton J. Crowell, RPh.....Pittsburg, KS
 James W. Cleland, RPh..... WaKeeney, KS
 Richard D. Bauer, RPh..... Coffeyville, KS
 Patrick A. Alkire, RPh..... Wichita, KS

Disciplinary Actions

Constance Lynn King, RPh, License No. 1-10866: Voluntary surrender of license to practice. Wichita, KS.

Crystal Gebler, Pharmacy Technician, Registration No. 14-06953: Registration revoked for diversion of controlled substance from her employer.

Samantha Haggard, Pharmacy Technician, Registration No. 14-08806: Registration revoked for failure to report known diversion of controlled substances from employer.

William Pollard, RPh, License No. 1-12224: Emergency suspension based on Missouri revocation.

New Regulation

The Board of Pharmacy held a public hearing on December 2, 2009, on K.A.R. **68-2-20 Pharmacists function in filling a prescription**. The regulation was amended unanimously to define an “authorized prescriber” as a practitioner, mid-level practitioner, or person authorized to issue a prescription by

the laws of another state. The regulation also defines, “legitimate medical purpose” as follows: “when used in regard to the dispensing of a prescription drug, shall mean that the prescription for the drug was issued with a valid preexisting patient-prescriber relationship rather than with a relationship established through an internet-based questionnaire, an internet-based consultation, or a telephonic consultation.”

Each pharmacist shall make a reasonable effort to ensure that any prescription regardless of the means of transmission has been issued for a legitimate medical purpose by an authorized prescriber. The regulation is aimed at rogue Internet pharmacies and is intended to instruct pharmacists on their responsibilities when filling Internet prescriptions. Internet prescriptions, per se, are not illegal but this regulation specifically prohibits a pharmacist from filling prescriptions written by a prescriber who has no patient-prescriber relationship. This does not mean that a prescriber cannot call in a prescription but if there are red flags regarding the patient-prescriber relationship, the pharmacist must use his or her professional judgment to determine the legitimacy of the prescription.

The Board will continue to review the outcome of this regulation with the Kansas Medical Society and others to make sure that this does not hinder any legitimate patient-prescriber relationship or legitimate telemedicine relationship.

Special Notice About the Kansas State Board of Pharmacy Newsletter

The Kansas State Board of Pharmacy has designated this *Newsletter* as an official method to notify licensees and registrants about information and legal developments. Please read this *Newsletter* and keep it for future reference because this *Newsletter* can be used in hearings as proof of notification of the *Newsletter's* contents.

Prescription Drug Monitoring Program

The Kansas State Board of Pharmacy is very pleased to announce that Christina Morris, JD, has accepted the position of prescription drug monitoring program (PDMP) program director. The Board unanimously approved Christina at their February 10, 2010 Board meeting.

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FDA and ISMP Warn of Potential Medication Errors for Dosing and Emergency Compounding of Tamiflu

Food and Drug Administration (FDA) issued a Public Health Alert regarding potential dosing errors with Tamiflu® (oseltamivir) for oral suspension. While United States prescriptions for liquid medicines are generally written in milliliters or teaspoons, Tamiflu is dosed in milligrams and packaged with a dispenser marked in milligram dosages. Errors where dosing instructions for the patient do not match the dosing dispenser have been reported to FDA. FDA advises that providers should write doses in milligrams if the dosing dispenser with the drug is in milligrams. Pharmacists should ensure that prescription instructions and the dosing device use the same unit of measure. More information can be accessed at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm183714.htm.

The Institute for Safe Medication Practices (ISMP) issued an alert to all health care professionals regarding a risk of dosing errors related to the concentration of pharmacy-compounded Tamiflu (oseltamivir phosphate) oral suspension being dispensed due to shortages of the manufacturer's oral suspension. The base concentration for the commercially manufactured Tamiflu oral suspension is 12 mg/mL. The directions for emergency compounding of Tamiflu oral suspension from Tamiflu powder capsules result in a 15 mg/mL oseltamivir base concentration. Incidents have occurred resulting in too large of a dose being dispensed to children. ISMP advises that prescribers communicate suspension doses in milligrams rather than by volume, and that, if experiencing shortages of commercial Tamiflu oral suspension, pharmacists communicate with area medical practices regarding the dosage error risk. More information may be found at the ISMP Web site at www.ismp.org/safetyalerts/20091015-Tamiflu.asp.

FDA Authorization for Use of Outdated Tamiflu Products Remains in Effect until April 2010

On October 30, 2009, FDA issued an Emergency Use Authorization (EUA) allowing pharmacists to dispense certain lots of expired Tamiflu for oral suspension as part of the federal government's response to the 2009 H1N1 influenza public health emergency. The declaration of emergency justifying the EUA remains in effect until April 26, 2010, unless it is terminated earlier, or extended. The authorized lots of Tamiflu for oral suspension, which were tested through the federal government's Shelf-Life Extension Program, are part of the Strategic National Stockpile and are listed on the FDA Web site at www.fda.gov/NewsEvents/PublicHealthFocus/ucm154962.htm. Additional information for health care professionals and the EUA letter are also available on the FDA Web site.

HIPAA and Quality – The Seven-Year Itch



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.

On April 24, 2003, an article in the *Wall Street Journal* noted that many health care providers “are going overboard to avoid violations” of the Health Insurance Portability and Accountability Act (HIPAA) privacy rule, which took effect on April 14 of that year. In fact, initial concern was that the rule might actually slow the transfer of protected health information and place patients at risk for harm, certainly the opposite of HIPAA's intended goal.

One particularly troubling area of confusion is whether listing the drug's intended purpose on a prescription violates the privacy rule. Initially, numerous organizations reported that physicians were reluctant to include this crucial information on prescriptions. But according to the US Department of Health and Human Services (HHS), listing a medication's purpose or the patient's diagnosis on a prescription does not violate the privacy rule. Although a patient's diagnosis or purpose for using a medication would qualify as protected health information, communicating this information on a prescription does not require separate, special authorization because the information is used for the purposes of treating the patient. A violation would occur only if the prescription form was then used for a purpose not defined by the HIPAA privacy rule, such as copying it for a marketing company.

Concerns were also raised that listing a purpose on prescriptions did not meet qualifications of providing only the minimum amount of information necessary to treat the patient. However, the “minimum necessary” rule does not apply when protected health information is disclosed between providers treating the same patient. ISMP firmly believes that the drug's intended purpose should be part of the “minimum amount of information necessary” on a patient's prescription. Pharmacists should never be expected to dispense a medication without knowing its intended use, which is typically the case in many community pharmacies. Knowing the

Compliance News to a particular state or jurisdiction should not be assumed as representing the law of such state or jurisdiction.)



medication's purpose helps pharmacists avoid confusion between products with look-alike names, as most products with similar names are used for different purposes. It also allows a double check to occur because the pharmacist is able to verify that the medication is being used appropriately for the patient's condition, and that it is dosed properly for its intended use.

The same arguments hold true for medication reconciliation. It is not a violation of the HIPAA privacy rules for community pharmacies to share patient information for the purposes of reconciling a patient's medication profile with hospitals because the minimum necessary rule does not apply when protected health information is disclosed between providers treating the same patient.

Seven years later, the best advice is still to use common sense when applying the HIPAA rules so that patient privacy and safety are not compromised.

USP Standards for Heparin Products May Require Dosage Adjustments

Heparin products using new standards began shipping on October 8, 2009, and may require that dosages are adjusted to achieve consistent potency, according to a FDA alert. New manufacturing controls issued by United States Pharmacopeia (USP) were adopted for heparin to guard against potential contamination. Included in the new controls were changes in the unit dose, making heparin about 10% less potent than the former unit used. More information can be found at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm184674.htm.

FDA Issues Alert, Seeks Assistance in Tracking Stolen Tylenol Arthritis and Tylenol PM Caplets

FDA has issued an alert regarding stolen Tylenol[®] Arthritis and Tylenol[®] PM products. Pharmacists should be wary of the following Tylenol products:

- ◆ Tylenol Arthritis Pain Caplet 150 count bottles with the following identifying information: UPC number 30300450838155, code number 8381500, and lot number 09XMC112.
- ◆ Tylenol PM 2-caplet packets with the following identifying information: UPC number 30300450482304, code number 4823000, and lot number 09XMC110.

The theft took place at a cargo terminal at the Jacksonville Port Authority in Jacksonville, FL on September 25, 2009.

FDA seeks assistance in tracking this theft and is asking pharmaceutical drug distributors and pharmacies that may receive offers for the stolen drug products, or that may have been sold stolen product, to contact FDA's Office of Criminal Investigations (OCI) by phone at 800/551-3989 or on the OCI Web site at www.fda.gov/ICECI/CriminalInvestigations/ucm123025.htm. Pharmacists should verify pedigrees they receive with any wholesale drug

purchases. News regarding the alert can be found at www.fda.gov/ICECI/CriminalInvestigations/ucm186269.htm.

FDA Warns Companies to Stop Marketing Unapproved Codeine Sulfate Tablets

On October 13, 2009, FDA warned four companies to stop marketing unapproved codeine sulfate tablets. The manufacturers and distributors that received warning letters are as follows:

- ◆ Lehigh Valley Technologies Inc in Allentown, PA
- ◆ Cerovene Inc in Valley Cottage, NY
- ◆ Dava International Inc in Fort Lee, NJ
- ◆ Glenmark Generics Inc USA in Mahwah, NJ

FDA regulations allow manufacturers 90 days to cease manufacturing of new product, and distributors 180 days to cease further shipment of existing products. Previously manufactured unapproved products may still be found on pharmacy shelves for a period of time. FDA advises that Roxane Laboratories markets FDA-approved codeine sulfate tablets and is able to meet the demand for the drug. For additional information about the warning letters, visit www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm186418.htm.

2010 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 2010 *Survey of Pharmacy Law* is now available.

The *Survey*, produced as a CD, 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 whether or not states license or register manufacturers separately from wholesalers.

Updates for the *Survey* were graciously provided by the state boards of pharmacy. In addition to the state boards of pharmacy's support, this year NABP requested data from numerous outside organizations for the *Survey's* prescribing authority and dispensing authority laws in Sections 24 and 25.

The *Survey* can be purchased for \$195 by visiting the publications section of the NABP Web site at www.nabp.net, downloading the publications order form, and mailing it to NABP Headquarters with a check or money order made payable to NABP. Credit card payments are accepted by phone.

All final-year pharmacy students receive the *Survey* free of charge through the generous sponsorship 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.

Christina has been with the Board of Pharmacy since 2003. She accepted a part-time administrative assistant position while she was pursuing her undergraduate degree at Washburn University. She received a bachelor of business administration business management degree in May of 2005 and graduated cum laude. She then received her juris doctor at Washburn University School of Law in May 2008. Christina accepted the position of assistant director of the Board of Pharmacy upon graduation from law school. During this time she assisted the executive secretary, as well as coordinated the PDMP program

In 2008 the legislature passed SB 491 charging the Board of Pharmacy with creating a prescription drug monitoring program. The legislation did not provide any funding for implementation of a program. During Christina's tenure with the Board of Pharmacy she has been instrumental in seeking funding for the PDMP outside of the standard collection of licensure and registration fees. On February 15, 2010, the National Association of State Controlled Substance Authorities (NASCSA) announced that the Kansas State Board of Pharmacy was the recipient of the 2010 PDMP Grant Program in the amount of \$20,072. NASCSA grants are the result of support from Purdue Pharma LLP to NASCSA for grants to assist states in providing enhancements and support for state PDMPs. This funding is in addition to a Harold Rogers grant from the federal Bureau of Justice Assistance awarded to the Board of Pharmacy in the amount of \$400,000. The Board was also awarded the Substance Abuse and Mental Health Services Administration National All Schedules Prescription Electronic Reporting Act formula grant totaling \$66,407. These grants are essential to the Board in order to meet the legislative mandate without raising license or registration fees.

A PDMP advisory committee of multidisciplinary stakeholders has been working with Christina the past year on drafting regulations. The regulations are important because they provide the specific guidelines and requirements of the PDMP. The advisory committee also settled on three drugs to put into the initial regulations as drugs of concern. These drugs are (1) any combination product containing butalbital, acetaminophen, and caffeine; (2) carisoprodol; and (3) tramadol. Since the recommendation of the committee, Drug Enforcement Administration has published a proposed regulation scheduling carisoprodol as a controlled substance. The regulations are scheduled for a public hearing on June 10, 2010, and then they will become final. The regulations can be reviewed on the Board Web site and we encourage you to comment on them prior to the public hearing if you have any concerns or comments.

The advisory committee has also developed a timeline and plan to put the software vendor request for proposal out by May. Once a vendor(s) is selected, implementation will begin with oversight by the Board of Pharmacy. An education program will include information on the use of a PDMP as well as how to reduce the diversion of scheduled medications. The advisory committee would like to include some basic pain management assessment and treatment information, as

well as some addiction assessment and treatment information. The educational program will be developed in conjunction with the health care community through the respective professional associations. According to other states, the implementation period will vary and can last up to 12 months but the Board's target date is October 2010. It is important to the Board of Pharmacy that there be communication with health care providers regarding the status of the program and required data submission.

The PDMP program involves the exchange of health information. Pharmacies will be submitting prescription drug utilization data to the PDMP. Prescribers and dispensing pharmacies will access this information for the care of their individual patients. Exchange of information through the PDMP will be conducted intrastate, as well as interstate.

The PDMP program director will be responsible for designing print materials that will be sent to everyone in the health care community. The materials will provide a thorough review of the PDMP and what part your pharmacy will play. The director will also provide face-to-face education around the state prior to going live with the program.

There is an abundance of reasons why Kansas is one of the many states to enact a prescription drug monitoring program. The emerging challenge of prescription drug abuse and misuse is a complex issue that requires a concerted effort by all Kansans. The Kansas PDMP, along with treatment and prevention programs that include outreach and education, is a key part of responding to this issue. The resulting impact of reducing diversion of controlled substances will also assist law enforcement. In addition, the Kansas PDMP will provide valuable and much needed data to health care providers and enhance their ability to manage chronic pain. In doing so, the benefits will be passed on to the residents of Kansas who are the patients of these health care providers. It is a cycle that will continue to benefit Kansans for years to come.

The Board appreciates the advisory committee members' hard work the past year on this very important program. We would like to express our thanks in particular to the pharmacists on the advisory committee. They are Karen Braman, RPh, MS; Max Heidrick, RPh; Phil Schneider, RPh; Lee Ann Bell, PharmD; and Harold Godwin, RPh. We also would like to thank Christina Morris and congratulate her on her appointment as the PDMP program director for the Kansas State Board of Pharmacy.

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