



Kansas State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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Fifty-Year Pharmacists

The Kansas State Board of Pharmacy is grateful to the following distinguished individuals who have contributed 50 years of service to the pharmacy profession and to the health and well-being of the citizens of Kansas. The Board is proud of their accomplishments, and they deserve the recognition and acknowledgement of their profession.

- Glen A. Hadaway.....Emporia, KS**
- Mary A. Donaldson.....Mulvane, KS**
- Andrew Bodner, Jr.....Prairie Village, KS**
- David E. Black.....Derby, KS**
- Charles E. Bishop.....Belle Plaine, KS**
- Jay S. Gruver.....Platte City, MO**
- Allen J. Gordon.....Hermosa Beach, CA**

Revisions to the Pharmacy Practice Act

On April 11, 2014, Governor Sam Brownback signed Senate Substitute for House Bill 2146 (SS HB 2146) into law, making several amendments to the Kansas Pharmacy Practice Act, which will become effective on July 1, 2014.

Amendments to K.S.A. 65-1626a expanded the definition of the practice of pharmacy to include the performance of collaborative drug therapy management (CDTM). A pharmacist may perform pharmaceutical-related patient care when physicians delegate those responsibilities through a collaborative practice agreement. Pharmacists and collaborating physicians will need to have a written protocol that outlines conditions or limitations to the collaborative practice agreement. Pharmacists may not act outside of their scope of practice, including altering physicians' orders or directions, diagnosing and prescribing drugs, or practicing independently. Physicians are responsible for the care of the patient at diagnosis and supervising the pharmacist throughout the drug therapy management process. The collaborative practice agreement must also be within the physicians' scope of practice and appropriate for the pharmacist's training and experience.

The bill also requires the Board and the Kansas State Board of Healing Arts to establish the Collaborative Drug Therapy Management Advisory Committee within 90 days of the act becoming effective. The purpose of the committee is to promote consistent regulation of pharmacists and physicians participating in CDTM as well as coordination of their respective boards. The committee will consist of seven members: one non-voting chairperson appointed by the Board of Pharmacy, three pharmacists, and three physicians. At least two pharmacists and two physicians on the committee shall have experience in CDTM. The Kansas Pharmacists

Association (KPhA) and the Kansas Medical Society will make committee member recommendations to their respective boards. The appointed members will serve terms of two years, with the exception of the initially appointed members. Two pharmacists and two physicians will serve two-year terms, and the remaining pharmacists and physician will serve one-year terms.

K.S.A. 65-1637b was amended to remove the authorization to refill a prescription drug that is not a controlled substance within 18 months of the written date. A prescription may be refilled 12 times within 12 months from the date of issue. An additional change to this statute addresses brand exchange, and requires electronically signed prescription orders to include the "dispense as written" designation on the electronic prescription if generic substitution is not allowed by the prescriber.

Amendments to K.S.A. 65-1632 give the Board authority to change the renewal dates of licenses, registrations, and permits. Currently, all retail dealer permits expire annually on February 28, pharmacist licenses and businesses expire on June 30, and pharmacy technician permits expire on October 30. The Board will adopt a schedule for license and permit renewal by regulation. With this change, license, registration, and permit fees may be prorated for periods that are less than the renewal period.

Language from K.S.A. 65-1643 was removed that previously allowed for a business entity registered to manufacture or distribute drugs at multiple facilities with joint ownership to do so under a single registration. All locations must have a separate registration or permit.

The final provision of SS HB 2146 permits the Board to require every registered pharmacy technician to pass one or more examinations identified and approved by the Board within a time specified by the Board after becoming registered. The Board may require any national pharmacy technician certification examination as a part of this requirement. Pharmacy technicians hold the highest number of active registrations with the Board and they have a high turnover rate. The addition of this statute will increase the competence of technicians while decreasing the number of on-the-job training hours. Pharmacy technicians will also be required to submit proof of continuing education. The Board worked on this issue with a task force the previous year and will continue to work with the task force in drafting rules and regulations related to implementation of the pharmacy technician provisions.

Revisions to the Controlled Substances Act

On April 17, 2014, Governor Brownback signed Senate Substitute for House Bill 2298, adding substances to Schedules I, III, and IV. With these additions, the Uniform Controlled Substances Act

Continued on page 4



New USP Webpage Answers Common Questions About USP Chapters <795> and <797>

In response to questions concerning United States Pharmacopeia-National Formulary (USP-NF) General Chapters <795> and <797>, USP has created a new frequently asked questions (FAQs) page on its website. The FAQs answer questions related to the Revision Bulletin for Chapter <795> that was issued on November 22, 2013, and became official on January 1, 2014. Among other topics, the FAQs address common questions regarding beyond-use dating and the differences between testing stability with strength (potency) or stability-inducing methods. The FAQs can be accessed at www.usp.org/support-home/frequently-asked-questions/compounding. Question four on the page includes a link to a USP article, "Strength and Stability Testing for Compounded Preparations."

Only You Can Prevent Look-Alike Sound-Alike Drug Names

 *This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization 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 provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Error Reporting Program. Report online at www.ismp.org. E-mail: ismpinfo@ismp.org.*

VESicare/Vesanoid Mix-Up. A prescriber's office sent an electronic prescription to the patient's pharmacy; the prescriber intended to prescribe **VESicare**® (solifenacin succinate) for overactive bladder but inadvertently selected **Vesanoid**® (tretinoin), which is used to induce remission of acute promyelocytic leukemia. The pharmacy technician entered the prescription for generic tretinoin; however, the pharmacy was unable to dispense the medication as the patient's pharmacy benefit manager required a prior authorization. The technician faxed a request and the prescriber's office replied back that VESicare was intended. Both of these products are available in 10 mg solid oral dosage forms, increasing the risk of confusion. Investigate strategies (eg, tall man letters) to differentiate these products on computer screens. Prescribers should include the indication for the drug with the prescription. As always, providing patient education, especially for new prescriptions, is a good strategy to intercept errors before they impact the patient.

Benazepril Confused With Benadryl. A pharmacist reported a mix-up between benazepril (**Lotensin**®) and **Benadryl**® (diphenhydramine). A patient faxed a request to the pharmacy to ask for her "benazpryl." The pharmacist who received the fax interpreted

it as Benadryl and placed a bottle of diphenhydramine in the bag for pick-up. Around this same time, the pharmacy went through a change in wholesaler and many manufacturers of generic products were changed. A few days later, a coworker of the patient picked up the medication (along with several others). The technician at the point-of-sale told the coworker that many of the manufacturers had changed recently and that some of the pills may look different. The patient received the diphenhydramine, filled her medication box with the capsules, and took diphenhydramine daily for three weeks before noticing she was unusually tired. When she brought the bottle back to the pharmacy, the error was recognized.

ISMP continues to receive reports of confused drug name pairs being involved in errors. ISMP wants to inform its readers of these drug name confusions so they may continue evaluating what measures they have in place to protect against these possible confusions.

Your Help Is Needed With Product Safety Testing. If you are a pharmacist, nurse, pharmacy technician, or other health care practitioner who is interested in furthering medication safety and error prevention, you can make a difference! Med-ERRS (a subsidiary of ISMP) is looking for assistance to help evaluate medication labels, drug packaging, and proposed drug names prior to submission by pharmaceutical and biotech companies for approval by Food and Drug Administration (FDA). The process is fun, simple, and easy. A small honorarium is paid. For more information or to sign up, visit www.med-errs.com and click on "Become a Reviewer."

FDA Issues Alert on Acetaminophen Products

In light of all the recent news alerts and warnings about the use of acetaminophen and acetaminophen-containing products, FDA issued a recommendation of importance to pharmacists, prescribers, and patients.

FDA recommends that health care providers consider prescribing combination drug products that contain 325 mg or less of acetaminophen. FDA also recommends that when a pharmacist receives a prescription for a combination product with more than 325 mg of acetaminophen per dosage unit that he or she contacts the prescriber to discuss a product with a lower dose of acetaminophen. A two-tablet or two-capsule dose may still be prescribed, if appropriate. In that case, the total dose of acetaminophen would be 650 mg (the amount in two 325 mg dosage units). When making individual dosing determinations, health care providers should always consider the amounts of both the acetaminophen and the opioid components in the prescription combination drug product.

FDA, in its MedWatch Safety Alert, reports that, "There are no available data to show that taking more than 325 mg of acetaminophen per dosage unit provides additional benefit that outweighs the added risks for liver injury. Further, limiting the amount of acetaminophen per dosage unit will reduce the risk of severe liver injury from inadvertent acetaminophen overdose, which can lead to liver failure, liver transplant, and death."

In January 2011, FDA asked manufacturers of prescription combination drug products containing acetaminophen to limit the amount of acetaminophen to no more than 325 mg in each tablet or capsule by January 14, 2014. FDA requested this action to protect consumers from the risk of severe liver damage that

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can result from taking too much acetaminophen. More than half of manufacturers have voluntarily complied with FDA's request. However, some prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit remain available. In the near future, FDA intends to institute proceedings to withdraw approval of prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit that remain on the market.

Boards of pharmacy have received inquiries from pharmacists about remaining stock of the higher dose acetaminophen and what procedures should be followed. The FDA recommendation notes that pharmacists are advised to contact prescribers and request a change in the prescription. If the prescriber is not willing to make the change in the prescription, unfortunately, there is no clear cut recommendation at this point as to whether to dispense the higher dose acetaminophen product. It would appear that the higher dose acetaminophen-containing products will be regarded by FDA as unapproved and delisted from FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book." Until this occurs, pharmacists must make a judgment regarding continuing to dispense the higher dose acetaminophen containing products in light of the FDA recommendation and concern for patient safety.

Some Rohto Eye Drops Products Recalled

The Mentholatum Company of Orchard Park, NY, has issued a voluntary recall of some Rohto® eye drop products due to a manufacturing review at the production facility in Vietnam involving sterility controls. The recall has been issued at the retail level and includes Rohto Arctic, Rohto Ice, Rohto Hydra, Rohto Relief, and Rohto Cool eye drops that were manufactured in Vietnam. Products made in other facilities are not affected by the recall. To date, there has been no evidence indicating the recalled products do not meet specifications, according to a press release.

The recalled products are sold over the counter at pharmacies and retail stores throughout the United States, and can be identified by the words "Made in Vietnam" on the side carton panel under the company name and address information as well as on the back label of the bottle. Lot numbers for the recalled products contain the letter "V." Distributors and retailers are being notified by letter to stop distributing the products and to follow the recall instructions provided by the company. Questions about the recall can be directed to The Mentholatum Company at 877/636-2677, Monday through Friday, 9 AM to 5 PM Eastern Time. FDA urges consumers and health care providers to report any adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information and Adverse Event Reporting Program. More information is available at www.fda.gov/Safety/Recalls/ucm382076.htm.

FDA Provides Compounding Law Implementation Information

FDA has provided implementation information on Title I of the recently passed Drug Quality and Security Act – known as the Compounding Quality Act – through its website.

Of note, FDA specifies that compounding entities may register as an outsourcing facility, which, under certain conditions, may be exempt from the Federal Food, Drug, and Cosmetic Act's (FD&C Act) approval and labeling requirements. Drugs produced by compounders that are not registered as outsourcing facilities must meet the conditions of Section 503A of the FD&C Act, which was amended by the new law, to qualify for certain exemptions.

The document adds, "If a compounded drug does not qualify for exemptions under either section 503A or 503B of the [FD&C Act], the compounded drug would be subject to all of the requirements of the [FD&C Act] that are applicable to drugs made by conventional manufacturers, including the new drug approval and adequate directions for use requirements." FDA also notes it will provide additional information about how the agency will interpret certain provisions of Section 503A at a later date.

The implementation information may be viewed at www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm375804.htm.

New e-LTP Fees Effective July 1, 2014

Supporting ongoing efforts to protect the integrity of its licensure transfer programs and to support the expansion of new technologies that are being implemented to enhance the program, the National Association of Boards of Pharmacy® (NABP®) is adjusting the fees for the Electronic Licensure Transfer Program® (e-LTP™).

Beginning July 1, 2014, the e-LTP fees will be adjusted as follows:

- ◆ The preliminary application and first state transfer fee will increase from \$350 to \$375
- ◆ Each additional state transfer will increase from \$50 to \$75
- ◆ Change of states will increase from \$50 to \$75
- ◆ Time extensions will increase from \$50 to \$75

The fees for e-LTP were last adjusted in 2010. More information about e-LTP is available in the Programs section of the NABP website at www.nabp.net. Additional questions about the fee adjustment may be directed to Neal Watson, licensure programs manager, at 847/391-4406, or at nwatson@nabp.net.



Pharmacists & Technicians:
Don't Miss Out on Valuable CPE Credit.
Set Up Your NABP e-Profile and Register for CPE Monitor Today!

Continuing pharmacy education (CPE) providers who are accredited by the Accreditation Council for Pharmacy Education (ACPE) have integrated CPE Monitor® into their systems and are requiring pharmacists and pharmacy technicians to provide an NABP e-Profile ID number and date of birth (MMDD) in order to process ACPE-accredited CPE credit.

Visit www.MyCPEmonitor.net to set up your NABP e-Profile and register for CPE Monitor and avoid possible delays in your CPE reporting.

CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their completed CPE credit electronically.

of Kansas more closely matches the Federal Controlled Substances Act. Schedule I was modified to include 14 hallucinogenic drugs, two cannabinoids, and a cannabinoid class. Anabolic steroids under Schedule III now include methasterone and prostanazol. Schedule IV was modified to include the new anti-obesity drug lorcaserin (Belviq®). As a reminder, pursuant to the Kansas State Board of Healing Arts Regulation K.A.R. 100-23-1, prescribers may not authorize more than a 30-day supply of an anti-obesity drug at a time without examining the patient and documenting findings of the physical exam and patient progress. Many prescribers are including refills on prescriptions for anti-obesity agents, and this is not allowed. These requirements are applicable to prescriptions that are written by a physician located out of state. Therefore, a prescription written with refills for an obesity drug can only be filled once. The prescription dies once the prescription is filled and the refills cannot be transferred to another state.

Regulatory Changes

A variety of proposed regulatory changes were adopted during the public hearing at the April Board meeting. Specifically, the Board approved a 20% reduction in licensure, registration, and permit fees across the board. The Board has an existing fee fund balance that should adequately support the needs of the agency for several years until the balance is at an acceptable level. The Board will continue to monitor the fee balance, but would like to make sure that it is not collecting more than is necessary to run the agency. The adopted fee changes can be found on the Board website under the link “Highlights of Changes.”

The Board amended K.A.R. 68-21-1 regarding the definition of patient identification numbers under the prescription monitoring program (PMP). “Patient identification number” shall mean “the patient’s unexpired temporary or permanent driver’s license number or state issued identification number. If the patient does not have one of these numbers, the dispenser shall use the patient’s insurance identification number. If the patient does not have an insurance identification number, the dispenser shall use the patient’s first, middle, and last initials, followed by the patient’s eight-digit birth date.” The Board is also drafting a guidance document to answer questions related to this specific regulatory change. The guidance document will be posted with the regulation change on the Board’s website.

A second change to the PMP regulations was made to K.A.R. 68-21-2 Electronic Reports. This regulation states that a “zero report” to the PMP will not cover more than a seven-day period in which no such drugs were dispensed, and be filed the day following the end of the period covered by the zero report. The purpose of this change was to allow the Board to know whether the pharmacy is reporting appropriately to the Kansas Tracking and Reporting of Controlled Substances (K-TRACS) program.

Pharmacist’s Responsibility

If you are the pharmacist-in-charge (PIC) of a pharmacy, it is your responsibility to ensure that all personnel you allow to perform pharmacy functions in the prescription area of the pharmacy are properly licensed or registered with the Board. K.S.A. 65-1663 states, “A pharmacy technician shall work under the direct supervision and control of a pharmacist. It shall be the responsibility of the supervising pharmacist to determine that the pharmacy technician is in compliance with the applicable rules and regulations of the board, and the supervising pharmacist shall be responsible for the acts and omissions of the pharmacy technician in the performance of the pharmacy technician duties.” You can verify the status of any credential the Board issues on the Board’s website.

In the event a compliance officer discovers anyone performing pharmacy functions without the necessary credentials, then all pharmacists present, including the PIC, will be identified in the

investigative report filed by the compliance officer. The Board will not fine the pharmacy, but will fine whichever supervising individuals are responsible for permitting the pharmacy technician to work without a current permit.

Poison Prevention Packaging Act

In 1970, Congress enacted the Poison Prevention Packaging Act (PPPA). It provided the United States Consumer Product Safety Commission (CPSC) the authority to establish child-resistant packaging standards to restrict children’s access to certain products. About 35 children a year die from unintentional poisoning, and around one million calls are placed to poison control centers for poison-related incidents. Ninety percent of poison accidents happen at home. The CPSC has advised the Board that it has received reports alleging that pharmacists are assuming that senior citizens want non-child-resistant packaging. Many child poisonings from prescription drugs occur when children are in their grandparents’ homes. Therefore, the Board will be assisting the CPSC to make sure that pharmacies are compliant with the PPPA and are meeting all federal requirements. Pharmacists are the primary party responsible for ensuring that prescription drugs are dispensed in child-resistant packaging.

Physician Assistant Dispensing

The 2014 Kansas Legislature passed HB 2673, which amended the Kansas Healing Arts Act and the Kansas Physician Assistant Licensure Act. The bill changed terminology, required participation in the Health Care Stabilization Fund as a “health care provider,” amended educational requirements, and changed some renewal standards. The practice of a physician assistant (PA) was also expanded to allow a PA, when authorized by a supervising physician, to dispense prescription-only drugs when dispensing is in the best interest of the patient and when pharmacy services are not readily available. PAs may dispense a quantity necessary for a 72-hour supply.

Useful Contact Information

Kansas State Board of Pharmacy	785/296-4056
	1-888/792-6273
K-TRACS	785/296-6547
Kansas State Board of Healing Arts	785/296-7413
	1-888/886-7205
Kansas Dental Board	785/296-6400
Kansas State Board of Nursing	785/296-4929
Kansas Board of Examiners in Optometry	785/832-9986
Drug Enforcement Administration	
(Kansas City)	913/825-4200
Food and Drug Administration, Center for	
Drug Evaluation and Research	1-855/543-3784
KPhA	785/228-2327
Kansas Council of Health-System Pharmacists	785/271-0208
Kansas Pharmacists Recovery Network	785/217-7091

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