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Kansas State Board of Pharmacy News

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Board Member Appointments

Governor Sam Brownback has made the following reappointments and appointments to the Kansas State Board of Pharmacy.

Congratulations to Jim Garrelts, PharmD, FASHP, on his reappointment to the Board. Dr Garrelts is senior director of pharmacy for Via Christi Hospitals Wichita and Via Christi Health. He received his bachelor of science degree in pharmacy from the University of Kansas (KU) and his doctor of pharmacy degree from the University of Texas at Austin and Health Science Center at San Antonio. He completed a specialty residency in adult medicine and pharmacokinetics at the Audie Murphy Memorial VA Hospital and University of Texas. Prior to becoming the senior director of pharmacy, he served in a variety of roles including clinical pharmacist, clinical coordinator, and manager of clinical pharmacy services at both Via Christi and Wesley Medical Center. He has held academic appointments with both the KU School of Pharmacy and School of Medicine. He has served in leadership roles with the Kansas Council of Health-System Pharmacists (KCHP), the American Society of Health-System Pharmacists (ASHP), and the Society of Infectious Diseases Pharmacists. He has received the Harold N. Godwin Lecture Award, the Legacy Award from the KCHP, and the ASHP Research Award. He developed the pharmacy practice residency program at Wesley Medical Center, serving as the residency program director. He has received research funding and has published extensively in pharmacy and medical literature. Dr Garrelts was first appointed to the Board in 2009, served as the Board's vice president in 2011, and served as Board president in 2012.

Governor Brownback also reappointed David Schoech, RPh, for his second term with the Board. Mr Schoech is from Columbus, KS, and he received his bachelor of science in pharmacy at the KU School of Pharmacy in 1982. Mr Schoech has previously owned and operated his own retail pharmacy in Columbus, and is currently a relief pharmacist for Walgreen Co, Parsons Family Pharmacy, Oswego Drug Store, Four States Pharmacy in Galena, KS, Wolker Drug in Baxter Springs, KS, and is the pharmacist-in-charge at Mercy Maude Norton Memorial Hospital. Mr Schoech is involved in many community and pharmacy associations such as Columbus Parks and Recreation Commission; Knights of Columbus (Charter Member); American Legion – Columbus Keith Reeves Post #3; KU Alumni Association – Life Member; Columbus Community Foundation; Columbus Lions Club; Columbus Chamber of Commerce; Columbus Country Club; Kansas Pharmacy Service Corporation; KU School of Pharmacy Advisory Council; and Kansas Pharmacists Association (KPhA). Mr Schoech received the KPhA Pharmacist of the Year award in 2006 and the National Community Pharmacists Association's 2011 National Preceptor of the Year Award. Mr Schoech served as the Board president from 2012-2013, and as their investigative member in 2009 and 2010.

The Board also welcomes Cheri Pugh as the consumer member of the Board. Mrs Pugh replaces Nancy Kirk and will serve a four-year term. Mrs Pugh is from Wamego, KS, and graduated with distinction from KU with a bachelor of arts in history with a minor in political science. She is a member of Kappa Alpha Theta and Phi Beta Kappa. Mrs Pugh is a broker and co-owner of McPeak and Pugh Real Estate in Wamego and was Broker of the Year for Manhattan Association of Realtors in 2013. She is currently the president of Wamego Hospital Foundation and has taken a lead role in fundraising for the hospital's expansion and renovation. Mrs Pugh is married, her husband is an attorney, and they have four grown children and several grandchildren.

CIPP and Kansas PRN to Host 22nd Annual Heartland PRN Conference

The Kansas Committee on Impaired Pharmacy Practice (CIPP) is the sponsor of the 22nd Annual Heartland Pharmacists Recovery Network (PRN) Conference. The conference will be held at the KU School of Pharmacy.

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Pharmacists Likely to Recommend OTC Medications, CHPA Reports

Patients most often seek a pharmacist's advice on treating coughs, headaches, migraines, and allergies, and 98% of pharmacists recommend or have no reservations recommending over-the-counter (OTC) products to treat such ailments, according to a recent survey. The Consumer Healthcare Products Association's (CHPA) report, "Understanding Trust in OTC Medicines: Consumers and Healthcare Provider Perspectives," presents the results of the survey, which was developed to better understand what drives consumer and health care provider trust in OTC products. The survey, developed and conducted by Nielsen and IMS, included over 1,100 consumer respondents, and over 500 health care provider respondents, composed of pharmacists, pediatricians, nurse practitioners, and primary care providers.

Pharmacists surveyed reported that they were more likely to recommend OTC products that demonstrated successful patient outcomes and consistent outcomes, and products known to be as efficacious as a prescription drug, and those containing ingredients known to be safe.

The survey also asked health care providers whether they recommended OTC products without, before, or in conjunction with recommending prescription drugs for certain symptoms. A majority of pharmacists surveyed, over 60%, recommend OTC medications to treat stomach symptoms and pain, without recommending a prescription treatment, and over 70% recommended OTC allergy, sinus, and flu medications without advising that a prescription drug is needed.

CHPA notes that with the expansion of patient self-care, OTC products will play an increasingly important role in health care. The potential for more prescription products to become OTC products in the new paradigm under consideration by Food and Drug Administration (FDA) could further impact this trend. As consumers are becoming more empowered in making health care decisions, they are also relying more on their pharmacist for medication advice. In fact, Nielsen and IMS findings show that multigenerational households, Hispanic households, and households who care for an adult outside of their home place a high value on pharmacist recommendations regarding selecting appropriate OTC medications, notes CHPA.

The full CHPA White Paper is available at *www.yourhealthathand.org/images/uploads/OTC_Trust_Survey_White_Paper.pdf.*

ISMP Study on Targeted Mandatory Patient Counseling

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 a recent study funded by a grant from Agency for Healthcare Research and Quality, ISMP evaluated the use of a combined checklist and patient information leaflet used during mandatory counseling sessions for consumers who pick up a filled prescription for 11 targeted medications:

- Opioid-containing analgesics
  - fentanyl patches
  - hydrocodone with acetaminophen
  - oxycodone with acetaminophen
- Anticoagulants
  - warfarin
  - enoxaparin
- Antidiabetic drugs (insulin analogs)
  - Humalog® (insulin lispro)
  - NovoLog® (insulin aspart)
  - Levemir® (insulin detemir)
  - Lantus® (insulin glargine)
  - Apidra® (insulin glulisine)
- Antineoplastic drug (non-oncologic use)
  - methotrexate

All 11 medications are on ISMP's list of high-alert medications dispensed from community pharmacies. Errors with high-alert medications may not be more frequent than errors with other medications; however, the consequences of errors with high-alert medications are often harmful. These 11 medications are also among the top 200 drugs dispensed in the United States, and many are used to treat chronic conditions, thus increasing the potential impact on public safety.

The medications were flagged in some manner to identify mandatory counseling opportunities. When a patient or patient representative picked up a flagged prescription, a pharmacist conducted a short counseling session (one to three minutes) that included the exchange of several key points on the checklist. At the end of the counseling session, the pharmacist provided the leaflet to the patient, along with a survey to complete and send back to ISMP.

Counseling sessions for these drugs were conducted for a consecutive period of four weeks, during which time, one trained ISMP staff member observed the counseling sessions for one day (six hours) to collect information on factors that facilitate or inhibit the counseling sessions. At the end of the four-week period of mandatory counseling, pharmacists at participating pharmacies were asked to complete a short mail-in survey regarding their perceived value of the process.

Results of the study showed that these consumer leaflets offer important safety tips for taking medication safely. Each leaflet begins with, "High-alert medicines have been proven to be safe and effective. But these medicines can cause serious injury if a mistake happens while taking them. This means that it is vitally important for you to know about this medicine and take it exactly as intended."

ISMP tested the readability, usability, and perceived value of the leaflets. Ninety-four percent of patients felt the leaflets provided great information or good information to know. Ninety-seven percent felt the information in the leaflets was provided in a way they could understand. Eighty-two percent of patients taking the drug for the first time and 48% of patients who had previously taken the medication reported learning something new. Overall, 85% of the patients felt they were less likely to make a mistake with the medication because they had read the leaflet.

The leaflets are available for download and can be reproduced for free distribution to consumers at *www.ismp.org/AHRQ/default.asp?link=ha.*

Generic Drug Substitution Requires Pharmacist Attention to State Laws and Regulations

While 40 years ago, most states forbade prescription drug substitution, almost all states now have drug product selection laws that allow, encourage, or mandate pharmacists to substitute generics for brand-name

drugs. These laws vary widely from state to state and pharmacists are therefore encouraged to review their state's substitution laws to ensure that they understand and comply with the state's requirements.

FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* publication, commonly known as the *Orange Book,* is generally considered the primary source for identifying suitable generic alternatives for a brand-name drug, and while not mandated by FDA regulations, the majority of states use the *Orange Book's* determinations of therapeutic equivalence to legally guide pharmacists in substituting generics.

State laws on generic substitution vary widely. A few states, such as Kentucky or Minnesota, follow a "negative formulary" approach, in which substitution is permitted for all drugs except those that appear on a particular list. Other states, including Massachusetts and Wisconsin, use a "positive formulary" approach, in which substitution is limited to the drugs on a particular list.

States also differ as to whether their substitution laws are permissive, thereby allowing a pharmacist to substitute a generic version of a brand-name drug, provided all prescription requirements are met, or mandatory, thereby requiring substitution. Prescription requirements may include such factors as the availability of a cheaper, therapeutically equivalent drug, the prescriber's specification that a brand-name drug be dispensed, or requiring the patient's or prescriber's consent. As reported in the 2013 NABP *Survey of Pharmacy Law*, 14 boards of pharmacy indicate that generic substitution falls into the "mandatory" category, while 38 boards indicate that their substitution laws are "permissive." Oklahoma law states that "[I]t is unlawful for a pharmacist to substitute without the authority of the prescriber or purchaser."

Other regulatory variations include states specifying the acceptable means for the prescriber to designate that substitution is not authorized, and states requiring patient consent prior to substitution.

The full article on this subject, which also reviews considerations regarding the accuracy of therapeutic equivalent determinations, is available in the June-July 2013 *NABP Newsletter,* which may be accessed in the Publications section of *www.nabp.net.*

NHF Provides Standards of Care for Pharmacies Serving Hemophilia Patients

For pharmacies that offer blood-clotting medications, organizations such as the National Hemophilia Foundation (NHF) emphasize the importance of being able to meet the specialized needs of their patients with bleeding disorders.

NHF's Medical and Scientific Advisory Council (MASAC) issued a standards-of-care recommendation in 2008 to assist pharmacies providing clotting factor concentrates for home use to patients with bleeding disorders. MASAC's guidelines are intended to be minimum standards of care and are divided into six areas:

As a brief overview of the MASAC guidelines, pharmacists wishing to meet the standards should:

1. Have a basic knowledge of bleeding disorders and experience with and knowledge of the full range of clotting factor concentrates, ancillary supplies, and hazardous waste disposal.

Pharmacies wishing to meet MASAC standards:

2. Should be able to provide a full range of available concentrates in all available assays and vial sizes, along with all necessary ancillary supplies, and hazardous waste disposal assistance as well as access to nursing services.
3. Should support reliable access to clotting factor for appropriate home treatment, by filling prescription orders within 48 hours, in the quantities prescribed, with expiration dates commensurate with the individual patient's needs.
4. Should be reliably open during regular business hours; provide 24-hour emergency access; and have an emergency action plan that allows patients to receive factor within 12 hours "in case of emergent need," with a goal of three hours "where logistically possible."
5. Should deliver products to the patient's desired location, meeting federal medication shipping standards, and providing an emergency number for patients to call in case of a problem with a delivery.
6. Should maintain patients' treatment prescription information along with maintaining records in compliance with state and federal requirements and be able to track the clotting factor products from manufacturer to patient, and participate in a recall information system.

The full article on this topic is available in the June-July 2013 *NABP Newsletter,* accessible in the Publications section of *www.nabp.net.* NABP notes that each state needs to review the standards recommended by MASAC to determine whether they coincide with existing state board of pharmacy requirements. NABP recognizes the unique patient needs of hemophiliacs, but also the responsibility of state boards of pharmacy to set required standards for medication dispensing and use. NABP is working with NHF to help the boards of pharmacy gain a better understanding of the medication needs of patients to help achieve uniformity in related regulations.

NABPLAW Online Now Includes Guam, Puerto Rico, and the Virgin Islands

The complete pharmacy acts and regulations of Guam, Puerto Rico, and the Virgin Islands are now included in **NABP***LAW*® Online, the comprehensive national data bank of state pharmacy laws and regulations provided by NABP. **NABP***LAW* Online's powerful search capabilities allow users to research subjects one state at a time or across all 50 states and included jurisdictions. More information about **NABP***LAW* Online and a link to the online subscription order form are available in the Programs section of the NABP Web site at *www.nabp.net/programs/member-services/nabplaw/.*

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Early registration and an open meeting will be held Friday, October 11, in the evening, and the conference continuing education (CE) will be all day Saturday, October 12, and until noon on Sunday, October 13, 2013.

The conference is dedicated to personal recovery, understanding substance abuse and its triggers, and the unique issues pharmacists face in relation to substance abuse and pharmacy practice. It is designed to provide pharmacists and pharmacy students with the opportunity to learn about treatment, recovery, and advocacy. The road can be a long and winding one but it does lead to recovery. This meeting is open to anyone who has an interest in the substance abuse topic or would like to learn more about CIPP and how to become a member.

To obtain an electronic brochure or to register for the 22nd Annual Heartland PRN Conference, you can e-mail Vicki Whitaker at Vicki@ksrx.org.

Prescriptions Received from PAs and APRNs

The Board has received calls concerning the failure of the physician assistant (PA) or advanced practice registered nurse (APRN) to include the name of the responsible physician (protocol) on the prescription.

The Board does not have any statutes or regulations that address this requirement. The Kansas State Board of Healing Arts regulates the PAs and the Kansas State Board of Nursing regulates the APRNs, and they both have laws addressing this requirement.

The PA statute is K.S.A. 65-18a08 (d) and it states:

> In all cases in which a physician assistant is authorized to prescribe drugs by a responsible physician, a written protocol between the responsible physician and physician assistant containing the essential terms of such authorization shall be in effect. Any written prescription order shall include the name, address and telephone number of the responsible physician. In no case shall the scope of the authority of the physician assistant to prescribe drugs exceed the normal and customary practice of the responsible physician in the prescribing of drugs.

The APRN regulation is K.A.R. 60-11-104a (c) and it states:

> Each prescription order shall meet the following requirement: (1) Include the name, address, and telephone number of the practice location of the advanced practice registered nurse; (2) include the name, address, and telephone number of the responsible physician; (3) be signed by the advanced practice registered nurse with the letters A.P.R.N.

If a prescription does not contain the above information, the PA or APRN is not in compliance with his or her own respective regulatory board's law. Both laws apply to non-controlled and controlled prescriptions. If you receive such a prescription, the Board encourages the pharmacy to call the PA or APRN and obtain the missing information. The pharmacy staff can add the missing information to the prescription. At the time of the call, the pharmacy staff should inform the PA or APRN of his or her requirement and offer to fax him or her the citation and requiring information of the appropriate law. If the problem is not corrected, the pharmacy should notify the Board of Healing Arts, the Board of Nursing, or your pharmacy inspector/compliance officer of the noncompliance. The goal is to inform the PAs and APRNs so that they can become compliant and at the same time not affect the patient from obtaining his or her medications.

New Board Office Employee

The Board has recently hired Jackie Yingling to handle the Board's accounts payables, receivables, CE audits, budget, and office management. Jackie has a degree in accounting and has worked for several private and public firms such as Arthur Andersen. Jackie is married and has two grown children, and one 16-year-old daughter who is still living at home. Jackie is learning the licensing area and has already made numerous improvements to the Board office. Jackie can be contacted at Jacking .Yingling@pharmacy.ks.gov or by contacting the Board office.

Useful Contact Information

Kansas State Board of Pharmacy.....785/296-4056
1-888/792-6273
Kansas Tracking and Reporting of Controlled Substances.....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
KCHP.....785/271-0208
Kansas PRN.....785/217-7091

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