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News

Arkansas State Board of Pharmacy

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Welcome New Staff and Board Members

Governor Asa Hutchinson recently appointed the following individuals to serve six-year terms on the Arkansas State Board of Pharmacy.

Cheryl Bryant, PharmD, is a pharmacist and health care supervisor for Walgreens pharmacies in the state of Arkansas. Her commitment to improving the lives of patients extends beyond her work with Walgreens. She volunteers monthly at the Westside Free Medical Clinic, where she dispenses medication and counsels patients. In 2010, she took a month-long mission trip to Honduras, where she ran a clinic in Los Leones, helping about 150 patients a day, most of whom traveled to the clinic from faraway villages. She did not always have access to the medications they needed, so she had to be resourceful and make do with what was available, which is a challenge many pharmacists face day to day, no matter the setting, when balancing insurance coverage, appropriate drug use, patient counseling, and out-of-pocket expenses.

In 2011, Dr Bryant was named Young Pharmacist of the Year by the Arkansas Pharmacists Association, and in 2012, she was chosen as one of *Arkansas Business* 40 Under 40 professionals. Dr Bryant is replacing former State Senator Percy Malone, PD, on the Board.

Carol Rader was appointed to the Board by Governor Hutchinson in August 2015. Mrs Rader is a retired human resources director for Hiram Walker/Pernod Ricard, USA, LLC, in Fort Smith, AR, and a former registered nurse. She graduated from Northside High School, completed her nursing degree at Westark Community College (now University of Arkansas at Fort Smith), earned a bachelor of science in organizational management from John Brown University, and a master of arts in human resources development from Webster University. During her tenure at Hiram Walker/Pernod Ricard, she was an active member of the Fort Smith Manufacturing Executives Association's (MEA) Human Resources Association, the Western Arkansas Human Resource Association, and was a member of the executive board of the MEA Healthcare Coalition.

Upon retirement six years ago, Mrs Rader volunteered for a one-year commitment as office manager for Saint Boniface Catholic Elementary School, where three of her six granddaughters attend. The one-year commitment turned into a most rewarding second career, as she began her sixth year in that role in August 2015. She is an active member of Saint Boniface Parish, and is on the Saint Boniface Catholic School Endowment Trust Board of Trustees and serves as its recording secretary. Carol has been married to her husband, Steve, for 31 years. She has two children: Dr Lori Boyd, an audiologist at the Center for Hearing in Fort Smith, and a son, Jody, who recently retired from the United States Navy and now resides in Ohio. Mrs Rader is replacing Mrs Sheila Castin on the Board.

The Board would also like to recognize and thank Dr Malone and Mrs Castin for their commitment to protecting the public health and welfare through their service on the Board.

The Board is pleased to announce the hiring of its chief legal counsel, **Chris Carnahan.** Mr Carnahan has been a licensed attorney since 2006, whose private casework included domestic relations, probate, general business, and criminal defense. Beginning in 2008, he was a deputy prosecuting attorney and county attorney in western Arkansas and maintained a limited private practice with the Tatum & Tatum law firm in Danville, AR. In 2011, Mr Carnahan transferred to the Twentieth Judicial District comprising Faulkner, Van Buren, and Searcy counties. He served as county attorney for Van Buren and Searcy counties, and received training through the National District Attorneys Association in Government Civil Practice in San Antonio, TX. Mr Carnahan's prosecution duties ran the gamut from speeding tickets to murder trials. He has tried more than 30 jury trials, and on a weekly basis prosecuted misdemeanor cases and represented the state at all bond hearings in Faulkner County. He has previously served as deputy city attorney for the City of Van Buren, AR, and city attorney for the towns of Oppelo, AR, Menifee, AR, Marshall, AR, and Holland, AR. He was also the city prosecutor for Fairfield Bay, AR, from 2011-2012.

Mr Carnahan has represented the state in mental commitment hearings, civil forfeiture actions, and juvenile matters in all seven counties where he was a prosecutor. He received his Drug Court certification in 2010 in Pittsburgh, PA, and he was part of the Drug Court treatment teams for Conway, Logan, and Yell counties. Additionally, he was the domestic battery prosecutor for District Court in Conway, AR, and his office's representative to the national Conference on Crimes Against Women in Dallas, TX, in 2014 and 2015. Mr

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FDA Issues Warning About Name Confusion for Brintellix and Brilinta

Due to similar brand names, there have been incidents where the antidepressant Brintellix® (vortioxetine) and the anti-blood clotting medication Brilinta® (ticagrelor) have been confused, resulting in prescribing and dispensing errors, warns Food and Drug Administration (FDA). The agency notes that no reports indicate that a patient has ingested the wrong medication; however, reports of prescribing and dispensing errors continue. FDA recommends that health care providers include the generic name of the medication in addition to the brand name, as well as the indication for use when prescribing these medications. Patients are advised to check their prescriptions to ensure that the correct medication was dispensed. More information is available in an FDA safety alert at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm456569.htm.*

Seven Persistent Safety Gaffes in Community/Ambulatory Settings That Need to Be Resolved!

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 Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

This is part two of a three-part series on seven persistent safety gaffes of 2014.

3) Vaccine Errors: Repetitive Errors Reported in the Last Decade

How often do DTaP (diphtheria and tetanus toxoids, and acellular pertussis) and Tdap (tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis) vaccine mix-ups need to occur before regulatory action is taken to prevent confusion? Whatever the number, we can say that health care providers have probably met that threshold! Yet, vaccine errors like this continue to occur at an alarming rate (based on those reported to ISMP alone). Vaccine mix-ups occur often because of age-dependent formulations of the same vaccine, similar vaccine abbreviations, similar vaccine containers and labels, and storage near each other. Confusion between the diluent and vaccine has led to administration of the diluent alone or use of the wrong diluent. With an unfortunate rise in parents choosing not to vaccinate their children or themselves, health care providers cannot continue to make errors when vaccinating those who choose to be immunized; the impact on both individual and community immunity may be far-reaching.

4) Wrong Patient Errors: Not Opening the Bag at the Point of Sale

Community pharmacies are vulnerable to dispensing correctly filled prescriptions to the wrong patient at the point of sale, a risk that is well substantiated in the literature. This error is not influenced by the attributes of a specific medication; thus, dispensing any prescription medication to the wrong patient at the point of sale carries a similar level of risk. Based on an ISMP study, the error happens frequently at an estimated rate of 1.22 per 1,000 prescriptions. Among approximately 56,000 community pharmacies in the United States, this error rate suggests that 332,755 prescriptions will be dispensed to the wrong patient each month, or about six every month per pharmacy. One of the most effective ways to prevent this error is to open the bag of filled prescriptions at the point of sale to verify that the medications are for the correct patient. According to the ISMP study, this simple step reduces the risk of error by 56%, yet few pharmacies follow this practice.

5) Disrespectful Behavior: A History of Tolerance in Health Care

Bullying, incivility, and other forms of disrespectful behavior are still rampant in health care and allowed to exist. Health care providers tolerate the behavior, remain silent, or make excuses in an attempt to minimize the profound devastation that disrespectful behavior causes. An ISMP survey conducted in 2003 clearly demonstrated the scope of disrespectful behavior among many levels of interdisciplinary staff, and an ISMP survey conducted a decade later demonstrates little progress. Disrespect diminishes a person's ability to think clearly, make sound judgments, speak up regarding questions, or avoid at-risk behaviors. Disrespectful behaviors also underlie a resistance to collaborate with others, follow procedures that promote safe practices, or implement new safety practices. While a culture of disrespect is harmful on many levels, its effect on patient safety makes it a matter of national urgency.

FDA Advises Caution Against Codeine for Treating Colds in Young Patients

FDA is evaluating the safety of using medicines containing codeine to treat patients under 18 years old for coughs and colds because of the possibility of severe side effects. Codeine, an opioid, may cause slowed or difficult breathing in children, especially for those who already suffer from breathing problems, the agency notes. FDA recommends that health care providers use caution when prescribing or recommending codeine for patients under 18 years old, and that parents and caregivers be alert for signs of shallow or noisy breathing, confusion, or unusual sleepiness. FDA is also considering a European Medicines Agency recommendation made in April to not give children under 12 codeine for coughs and colds, and to not use codeine for patients 12 to 18 years old who have asthma or other chronic breathing problems. More information is provided in an FDA safety alert available at *www.fda.govSafety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm453379.htm.*

Daytrana Patch May Cause Permanent Skin Color Changes, FDA Warns

In June 2015, FDA warned health care providers and consumers that Daytrana®, a methylphenidate transdermal system prescribed for treating attention deficit hyperactivity disorder, may cause permanent loss of skin color in the affected area. FDA has added a new warning to the drug label to describe this skin condition, known as chemical leukoderma. Chemical leukoderma is a skin condition that causes the skin to lose color as a result of repeated exposure to specific chemical compounds, according to an FDA safety alert. The condition is not physically harmful, but it is disfiguring.

FDA advises patients and caregivers to watch for new areas of lighter skin, especially under the drug patch, and to immediately report any changes to their health care providers. Patients should not stop using the Daytrana patch without consulting a health care provider. FDA also recommends that providers for patients who experience these skin color changes consider alternative treatments. More details are included in the FDA safety alert available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm452595.htm.*

FDA Expands NSAID Warning Labels Regarding Risks of Heart Attack, Stroke

The labels of certain non-steroidal anti-inflammatory drugs (NSAIDs) will soon contain more detailed information about the risk that the drugs may contribute to heart attack and stroke, reports FDA. Such warnings have been on prescription and over-the-counter NSAIDs since 2005, but the new requirements take into account new data showing that the risk of heart attack and stroke occurs even during the first few weeks of taking an NSAID. People who have cardiovascular and other heart problems are at even greater risk of adverse effects. An FDA alert available at *www.fda.gov/ForConsumers/ConsumerUpdates/ucm453610.htm* provides more details.

Baxter International, Inc, Recalls Three Lots of IV Solutions Due to Particulate Matter

In July 2015, Baxter International, Inc, voluntarily recalled two lots of intravenous (IV) solutions distributed to hospitals and other health offices because of the presence of particulate matter identified as an insect. The problem was identified before patient administration and no adverse health effects have been reported. The recall affects 0.9% sodium chloride injection, USP 50 mL and 100 mL, lot numbers P319921 and P327635, which were distributed to US customers between October 7, 2014, and July 14, 2015. Additional information is available in an FDA press release at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm455421.htm.*

Baxter also voluntarily recalled one lot of IV solution to the hospital/user level because of the potential for leaking containers, particulate matter, and missing port protectors. This recall affects 0.9% sodium chloride injection, USP (AUTO-C) with lot number C964601 (National Drug Code 0338-0049-03; expiration date: April 30, 2016). This recalled lot was distributed to customers and distributors nationwide between January 22, 2015, and February 12, 2015. Leaking containers, particulate matter, and missing port protectors could result in contamination of the solution and, if not detected, could lead to a bloodstream infection or other serious adverse health consequences, explains FDA. The agency notes further that "injecting a product containing particulate matter, in the absence of in-line filtration, may result in blockage of blood vessels, which can result in stroke, heart attack or damage to other organs such as the kidney or liver. There is also the possibility of allergic reactions, local irritation and inflammation in tissues and organs." More information about this recall is available in an FDA safety alert at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm456793.htm.*

FDA Warns Against Unapproved Prescription Ear Drops

FDA has ordered the manufacturers of certain prescription ear drops to stop making and distributing the products because they are not FDA-approved. The product labels do not disclose that they lack FDA approval, and health care providers may not be aware of the unapproved status, notes FDA. The agency took action against unapproved prescription otic drug products containing these ingredients:

- benzocaine;
- benzocaine and antipyrine;
- benzocaine, antipyrine, and zinc acetate;
- benzocaine, chloroxylenol, and hydrocortisone;
- chloroxylenol and pramoxine; and
- chloroxylenol, pramoxine, and hydrocortisone.

These drugs are frequently given to relieve ear swelling and pain in young children, and FDA took this action to protect patients from the risks of taking unapproved drugs with no proven safety or effectiveness information. Further, such drugs may be contaminated or manufactured incorrectly, notes the agency. More information is provided in an FDA news release available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm453348.htm.*

Acino Products in New Jersey Ordered to Stop Selling Rectacort-HC and GRx HiCort 25

Under the direction of FDA, a federal judge for the District of New Jersey has ordered Acino Products, LLC, of Hamilton, NJ, to stop selling and destroy certain unapproved and misbranded prescription drugs in its possession.

According to FDA, Acino has marketed unapproved hydrocortisone acetate 25 mg suppositories, under the brand names Rectacort-HC and GRx HiCort 25, for treatment of medical conditions including inflamed hemorrhoids, chronic ulcerative colitis, and other inflammatory conditions. The drugs have not been FDA-approved and also fail to carry adequate directions for use on their labels. Acino continued to market and sell the products despite several warnings from FDA investigators. The FDA news release is available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm453466.htm.*

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Carnahan is licensed in the state of Arkansas and before the Eastern and Western US District Courts in Arkansas. He lives with his wife, Ashley, in Conway, where he is a member of the Conway Men's Chorus, a sustaining member of Conway Community Arts Association, a former Faulkner County Election Commissioner, and is active in community affairs.

2015 Arkansas Prescription Drug Abuse Summit

The Board hopes that you will consider joining us at the 2015 Arkansas Prescription Drug Abuse Summit to be held in Hot Springs, AR, November 3, 2015. This year's summit will be held at the Hot Springs Convention Center and will include an opportunity to gain continuing education during a day-long conference structured to include breakout sessions for health care professionals to delve further into the problems associated with the abuse of and addiction to prescription drugs. Please visit *www.arkansasag.gov* and *www.cji.edu* for details.

Phantom Pharmacists-in-Charge

The Board continually sees and hears of pharmacies that tell Arkansas-licensed pharmacists that they will pay them, contract with them, or "hire" them to be the pharmacist-in-charge (PIC) of record for an application, but he or she will be replaced as the PIC by the time anything is shipped. To be clear, Board applications specifically ask for the name of the PIC and also ask for the number of hours this person will be working in the pharmacy. The Board has even had out-of-state applications where the named PIC has an Arkansas license but does not hold a license to legally work in the state where the pharmacy is located. In many instances the PIC does not even live in the state where the pharmacy is located and, by all appearances, is being paid for "contract work" or as a "consultant" and is not present in the permitted pharmacy. There is no such thing as an "application PIC," and the rules and regulations for Arkansas-licensed pharmacies are quite clear as to the responsibilities of a PIC. The Board considers applications with "phantom PICs" to be fraudulent applications, and will pursue action against the pharmacy and pharmacist when discovered (emphasis added).

04-00-0002—Time Requirements for Pharmacies and for the Pharmacist in Charge

(a) Unless expressly provided otherwise in Board regulations, all pharmacies in Arkansas shall be open a minimum of forty (40) hours per week and have on duty an Arkansas licensed pharmacist in charge. The pharmacist in charge shall be on duty in the pharmacy:

(1) a minimum of fifty (50) percent of the pharmacy hours for pharmacies open 64 hours per week or less, or

(2) at least thirty-two (32) hours per week for pharmacies open more than sixty-four (64) hours per week

04-04-0001—Out of State Pharmacy Regulation

Out of State pharmacies shall comply with the following qualifications to be, and remain, licensed in Arkansas by the Board.

(a)

(1) The pharmacy holds a current license in good standing in the state(s) in which it is located.

(2) Each pharmacist dispensing drugs into Arkansas shall be licensed as a pharmacist in Arkansas or in the state where he practices if that state has standards of licensure at least equivalent to those of Arkansas.

(b) A pharmacist currently licensed in Arkansas, shall be named in the application and shall serve as the pharmacy's pharmacist in charge for the Arkansas permit and as the contact person for communications by the Board. **Said Arkansas Pharmacist shall be an employee of the out of state pharmacy who shall be present at the pharmacy's physical location at least fifty (50) percent of the number of hours per week the pharmacy is open up to a maximum of twenty (20) hours per week.** The pharmacist in charge for the Arkansas Permit need not be the same person as the pharmacist in charge of the pharmacy pursuant to the law in the state in which the pharmacy is located.

(1) That pharmacist will be responsible for receiving and maintaining publications distributed by the Board.

(2) If at anytime the pharmacist so designated as the pharmacist in charge for the Arkansas permit shall leave that capacity or not be able to serve in that capacity, the pharmacy shall notify the Board within ten (10) calendar days and designate another Arkansas licensed pharmacist to perform this function by written notice to the Board within thirty (30) calendar days.

Multi-Dose Packaging

Pharmacies wishing to utilize multi-dose packaging systems must have a signed memorandum of understanding (MOU) with the Board prior to dispensing any multi-dose prescription containers. It is important to note that the MOU from the Board does not allow for use of multi-dose systems for nursing home patients at this time. Multi-dose packaging can be utilized for retail customers, assisted living facilities, and jails/prisons once the agreement is signed. If you need a MOU for multi-dose packaging, please contact the Board office or download the Multidose Memorandum of Understanding under the Forms and Instructions section on the Board's website.

Regulation Changes

On October 8, 2014, the Board held a public hearing at the Arkansas State Board of Pharmacy, 322 South Main, Suite 600, Little Rock, AR 72201. The following regulation changes were considered and approved for adoption. These changes were later reviewed by legislative council and became effective December 29, 2014. Updated versions of these regulations are available on the Board's website.

♦ **Regulation 07 – Drug Products/Prescriptions**

Changes adopted language defining how pharmacists may therapeutically substitute a therapeutically equivalent product if allowed by a prescriber in accordance with Arkansas Act 274 of 2013. The following language is now reflected in Regulation 07:

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07-00-0010 – Therapeutic Substitution

A pharmacist may substitute a therapeutically equivalent drug that is at a lower cost to the patient only after the prescriber grants such authorization for each prescription. A prescriber may authorize a pharmacist to dispense a therapeutically equivalent drug product as part of a written prescription as defined to include a written, oral, faxed, or electronic prescription by indicating Therapeutic Substitution Allowed or May Therapeutically Substitute or abbreviating "TSA" or "MTS" as part of the prescription verbally, in writing or by utilizing a separate signature line to show such authorization.

(a) Therapeutic equivalence may be established with clinical publications comparing dosages of drugs in a therapeutic class.

(b)

(1) Before dispensing, the pharmacist shall discuss verbally any suggested substitution with the patient and inform the patient that the patient has a right to refuse the substitution. This discussion shall include without limitation:

(A) Notification to the patient that the therapeutically equivalent drug does not contain the identical active ingredient present in the prescribed drug; and

(B) All differences in dosage and frequency between the prescribed drug and the therapeutically equivalent drug.

(c) The pharmacist shall send notice of the substitution to the prescriber in writing or by electronic communication within twenty-four (24) hours after the drug is dispensed to the patient.

(d) This section does not apply to specific acts of drug therapy management or disease state management delegated to a pharmacist based upon a written protocol or patient care plan approved by a physician under § 17-92-101(16)(A)(ix); (Adopted 12/29/2014)

On Tuesday, June 9, 2015, at 11 AM, the Board held a public hearing at the Board office in Little Rock. The following regulation changes were considered and approved for adoption. These changes were later reviewed by legislative council and became effective July 22, 2015. Updated versions of these regulations are available on the Board's website.

- **Regulation 03 – Pharmacy Technicians**
  Changes modified language to increase the number of pharmacy technicians that may be supervised by pharmacists to a 3:1 ratio in both retail and hospital settings. Changes also removed antiquated language that held restrictions for the manner in which a pharmacy technician could obtain a permit to remove an obstacle from this process, and clarified that pharmacy students on educational rotations would not count in the intern-to-pharmacist ratios.
- **Regulation 05 – Long-Term Care Facilities**
  Changes modified language allowing the use of emergency kits in licensed in-patient hospice care facilities and nursing homes.
- **Regulation 09 – Pharmaceutical Care/Patient Counseling**
  Changes modified language regarding the Medications Administration Advisory Committee to reflect language in Act 1100 of 2015.
- **Regulation 11 – Criminal Background Checks**
  Changes removed any exemptions from obtaining a criminal background check for pharmacists outside of Arkansas. This regulation is being updated to reflect changes to Arkansas law pursuant to Act 532 of 2015.

Prescription Drug Take-Back Success Ongoing and ARTakeBack.org

The April 2015 Arkansas drug take-back event resulted in a total of 20,020 pounds of unused medications being gathered, which once again surpassed the Board's hopes for this event. As you may know, this year's April event was specific to Arkansas as Drug Enforcement Administration (DEA) did not sponsor a national take-back event this spring. Nonetheless, the Arkansas DEA has continued to be involved in these events, as well as the Board's partnerships with the Arkansas National Guard and many law enforcement agencies. The cumulative efforts of Arkansas take-back events have resulted in an estimated 200 million doses of drugs being removed from homes and destroyed responsibly so that they can no longer be a risk to someone else. This fact is astounding when considering that without this service, some pounds of medications might still be sitting around the state in closets, medicine cabinets, and bathrooms. As a reminder when dealing with your patients, the Board partnered with the City of Benton Police Department, DEA, and former State Drug Director Fran Flener on the *www.ARTakeback.org* website that has been and will continue to be updated with information surrounding drug disposal and destruction. The last DEA-sponsored National Prescription Drug Take-Back event on September 26, 2015, resulted in another 17,870 pounds of medications being returned in Arkansas.

Special Notice About the Arkansas State Board of Pharmacy Newsletter

The Arkansas State Board of Pharmacy has designated this *Newsletter* as an official method to notify pharmacists licensed by the Board about information and legal developments. Please read this *Newsletter* and keep it for future reference because this *Newsletter* will be used in hearings as proof of notification of the *Newsletter's* contents. Please contact the Board office (501/682-0190) if you have questions about any of the articles in this *Newsletter.*

Arkansas Pharmacy Support Group Help Line
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