



# Arkansas State Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

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## Arkansas State Board of Pharmacy Celebrates 125 Years of Service

During the June Arkansas State Board of Pharmacy meeting, the Board held a reception to celebrate 125 years of service to Arkansans. In recognition of the enabling legislation introduced by the Arkansas Pharmacists Association and enacted by the legislature and governor on March 22, 1891, the Board wanted to host its partners in protecting the health and welfare of Arkansans in dealing with prescription drug issues.



John Clay Kirtley (left) and Lisa R. Barnhill (right)

During the reception, the Board also chose to honor Little Rock, AR, Drug Enforcement Administration (DEA) Diversion Group Supervisor Lisa R. Barnhill with an honorary doctor of pharmacy license. This has only been done a handful of times in the Board's history and only in situations where someone has shown a true commitment to helping protect the public health and welfare in regard to prescription drugs. The Board recognized Lisa's tireless efforts in working with the Board over the years to build relationships between pharmacists, pharmacies, and law enforcement, as well as her service in developing programs that have resulted in continuing education (CE) sessions. Board Executive Director John Clay Kirtley stated:

During her tenure in Arkansas, Lisa has been an invaluable resource to both pharmacists and pharmacies for questions and clarifications of federal controlled substance [CS] laws and regulations and her efforts have truly changed the attitude of many healthcare professionals in Arkansas to show that DEA is a partner and friend in our endeavors rather than just another enforcement agency. Lisa has also been a valuable partner in cases with the Board where we have been able to join forces on investigations for the best possible outcomes. I would be remiss if I did not mention three major projects that Lisa has been vital to in our state. First, the Arkansas Prescription Drug Abuse Summit[:] not only is Lisa a key member to our Summit but she has also served as a presenter. In conjunction with the

Board of Pharmacy, the [United States] Attorney's Office and the Arkansas Drug Director's Office, Mini-Drug Summits were also held in different areas of the state. Second, with Lisa's help and guidance, Arkansas is ranked number three per capita in the collection of drugs in the National Drug Take-Back Initiative. Such results were accomplished through working with our state partners in putting a "drop box" in every county in the state. Last, during the 2015 legislative session, Lisa's direct knowledge and action resulted in her idea to suggest a 'Duty to Report' law which was drafted, passed and was signed by the Governor.

## 2016 Arkansas Prescription Drug Abuse Summit

The Board hopes that you will consider joining us at the 2016 Arkansas Prescription Drug Abuse Summit to be held in Little Rock on November 3, 2016. This year's summit will be held at the Embassy Suites in Little Rock and will include an opportunity to gain CE 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 the [Board website](#) as well as [www.arkansasag.gov](http://www.arkansasag.gov) and [www.cji.edu](http://www.cji.edu) for additional details in the future.

## Welcome New Board Members

Governor Asa Hutchinson recently appointed the following individuals to serve terms on the Board.

### Dr James A. Burgess, DDS, Public Member, Greenwood, AR



Dr James A. Burgess, DDS, was appointed to the Board by Governor Hutchinson in December 2015. Dr Burgess opened his dental practice in Greenwood in 1959 after graduating from the University of Arkansas and the University of Kansas City Dental School (now the University of Missouri-Kansas City School of Dentistry). Since 1959, he has served people in Sebastian, Crawford, Scott, and Logan counties, offering his services to those in need of dental care regardless of their ability to pay.

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## **FDA Calls for Review of Opioids Policy, Announces Action Plan**

As part of a broad national campaign to address opioid abuse, dependence, and overdose, Food and Drug Administration (FDA) Deputy Commissioner for Medical Products and Tobacco, Dr Robert Califf, along with other FDA leaders, developed a comprehensive action plan to reassess the agency's approach to opioid medications. The objective of the plan is to "focus on policies aimed at reversing the epidemic, while providing patients in pain access to effective relief," indicates the FDA news release. FDA's plan is to:

- ◆ Re-examine the risk-benefit paradigm for opioids and ensure that the agency considers their wider public health effects;
- ◆ Convene an expert advisory committee before approving any new drug application for an opioid that does not have abuse-deterrent properties;
- ◆ Assemble and consult with the Pediatric Advisory Committee regarding a framework for pediatric opioid labeling before any new labeling is approved;
- ◆ Develop changes to immediate-release (IR) opioid labeling, including additional warnings and safety information that incorporate elements similar to the extended-release/long-acting (ER/LA) opioid analgesics labeling that is currently required;
- ◆ Update Risk Evaluation and Mitigation Strategy requirements for opioids after considering advisory committee recommendations and review of existing requirements;
- ◆ Expand access to, and encourage the development of, abuse-deterrent formulations of opioid products;
- ◆ Improve access to naloxone and medication-assisted treatment options for patients with opioid use disorders; and
- ◆ Support better pain management options, including alternative treatments.

FDA will also seek guidance from outside experts in the fields of pain management and drug abuse. The National Academies of Sciences, Engineering, and Medicine has been asked by FDA to help develop a framework for opioid review, approval, and monitoring that balances individual need for pain control with considerations of the broader public health consequences of opioid misuse and abuse. The news release is available on FDA's website at [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm484765.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm484765.htm).

## **More Selected Medication Safety Risks to Manage in 2016**

 *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](http://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](http://www.ismp.org). Email: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org).*

## **Manufacturer Drug Labeling, Packaging, Nomenclature – Per Liter Electrolyte Content on Various Sizes of Manufacturers' IV Bags**

The way electrolyte concentrations are expressed on intravenous (IV) bags in volumes less than or greater than one liter has tripped up many practitioners over the years. Concentrations are listed per liter, not per container volume. For example, a 250 mL 0.9% sodium chloride injection container label lists the sodium chloride content as 154 mEq/1,000 mL, rather than 38.5 mEq/250 mL. Commercially available parenteral nutrition products available in containers greater than one liter also express the electrolyte ingredients "per liter."

An error occurred while a pharmacist was preparing a bag of 3% sodium chloride after the pharmacy unexpectedly ran out of the commercially available bags. The pharmacist mistakenly set the proportion up as  $154 \text{ mEq}/0.9\% = x/3\%$  and calculated that he needed 513 mEq of sodium chloride, when he actually only needed 256–257 mEq of sodium chloride for a 500 mL bag ( $77 \text{ mEq}/0.9\% = x/3\%$ ).

For single- and multiple-dose injectables, the United States Pharmacopeial Convention (USP) requires the strength per total volume as the primary, prominent display on the label, followed in close proximity by the strength per mL enclosed in parentheses. This should apply to large volume parenterals as well. Until it does, pharmacists who calculate electrolyte quantities should seek out an independent double check. Sufficient quantities of commercially available products should be used whenever possible. For products that routinely require admixture, an instruction sheet should be available to guide the process.

## **Patient Education – Discharging Patients Who Do Not Understand Their Discharge Medications**

Despite the importance of teaching patients about the medications to take after discharge, studies suggest health care providers are not successfully preparing patients for the transition home. Between 30% and 70% of patients make a medication error in the immediate weeks following hospitalization,<sup>1-3</sup> and the Centers for Medicare & Medicaid Services reports an average national hospital readmission rate of 17.5% to 19.5%.<sup>6</sup> The discharge process is often rushed and interrupted, making it difficult to ensure patients know what medications to take, the correct doses, and how to take them after discharge. Immediately prior to discharge is not an ideal time for education either, as patients may be overwhelmed with the amount of information being provided at once.

Medication errors that occur during the first few weeks after discharge from the hospital can cause significant harm. In fact, one study showed that almost a quarter of all post-discharge errors were considered serious or life-threatening, and that



most of these errors happened within the first 14 days after discharge.<sup>5</sup> The highest predictors of post-discharge errors included low health literacy and low subjective numeracy (self-reported measure of the ability to perform mathematical tasks and the preference for numerical versus prose information (ie, ordinary words)).<sup>4</sup>

Perhaps this risk is best addressed with a redesigned discharge process that facilitates the most effective means of teaching patients about their medications, initiating education earlier in the hospital stay, and providing post-discharge support.

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#### USP Publishes Chapter on Handling Hazardous Drugs in Health Care Settings

A new general chapter, <800> *Hazardous Drugs—Handling in Healthcare Settings*, has been published as part of a suite of health care quality standards included in the *United States Pharmacopeia – National Formulary (USP–NF)* by USP to help prevent and/or limit hazardous drug exposures in health care. The standard applies to all health care personnel, such as physicians, nurses, veterinarians, pharmacists, and technicians, and all health care facilities where hazardous drugs are handled or manipulated, including their storage and distribution. Health care facilities have more than two years to conform to the new requirements and have until July 1, 2018, to implement the new standard, indicates a USP press release, which is available at [www.usp.org](http://www.usp.org) in the News section. General Chapter <800> is available in both the First Supplement to *USP 39–NF 34* and the *USP Compounding Compendium*.

#### FDA Provides Training Video on Keeping Medications Safe in Emergency Situations

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the February 2016 Drug Info Rounds video, “Emergency Preparedness – Keeping Medications Safe,”

pharmacists discuss educating patients about having a plan in place for emergency medication and medical supplies and the resources available for pharmacists to use when advising their patients. Drug Info Rounds is developed with contributions from pharmacists in FDA’s Center for Drug Evaluation and Research, Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at [www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm](http://www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm).

#### FDA Requires Class-Wide Labeling Changes for IR Opioid Analgesics

FDA is requiring class-wide safety labeling changes for IR opioid pain medications, which will include a new boxed warning about the serious risks of misuse, abuse, addiction, overdose, and death. The announcement is part of the agency’s effort to educate prescribers and patients about the potential risks related to opioid use. FDA is also requiring several safety labeling changes across all prescription opioid products to include additional information on the risk of these medications. The new requirements are part of a plan to reassess the agency’s approach to opioid medications. The plan is focused on reversing the epidemic of abuse and overdose while still providing patients in pain access to effective relief, indicates the FDA news release at [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm?source=govdelivery&utm\\_medium=email&utm\\_source=govdelivery](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery).

Further, FDA is requiring updated labeling for all opioids (both IR and ER/LA products) to include safety information about potentially harmful drug interactions with other medicines that can result in a serious central nervous system condition called serotonin syndrome. In addition, updated labeling will include information about opioid effects on the endocrine system, including a rare but serious disorder of the adrenal glands (adrenal insufficiency) and decreased sex hormone levels (androgen deficiency). More information about these risks is available in FDA’s Drug Safety Communication announcement, available at [www.fda.gov/Drugs/DrugSafety/ucm489676.htm](http://www.fda.gov/Drugs/DrugSafety/ucm489676.htm).

#### FDA Issues Alert Regarding All Unexpired Sterile Drug Products Produced by Medaus Pharmacy

On April 1, 2016, FDA alerted health care providers and patients not to use products marketed as sterile from Medaus Pharmacy in Birmingham, AL. Insanitary conditions, including poor sterile production practices, were identified by FDA investigators during a recent inspection at Medaus’ facility. The affected products were distributed nationwide and internationally. The alert applies to all unexpired drug products that are intended to be sterile. Health care providers should check their medical supplies, quarantine any drug products marketed as sterile from Medaus, and not administer them, indicates the FDA Safety Alert, available at [www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsForHumanMedicalProducts/ucm493871.htm](http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsForHumanMedicalProducts/ucm493871.htm).

Although semi-retired, Dr Burgess continues to volunteer at the Community Dental Clinic in Fort Smith, AR, where he provides basic dental care to thousands of people and helped start the denture program. He has been an integral part of the Community Dental Clinic since 1989. Dr Burgess was instrumental in getting Delta Dental into Arkansas. He serves as an adjunct professor at the University of Arkansas at Fort Smith Dental Hygiene School.

Dr Burgess belongs to several professional organizations and has served on the boards of several institutions. He is a member of the American Dental Association, Arkansas State Dental Association, and Fort Smith Dental Association, and he served on the Arkansas State Board of Dental Examiners. He has served as a board member for the University of Arkansas at Fort Smith, the Sparks Regional Medical Center, and the Sparks Regional Medical Center Foundation.

Dr Burgess is replacing Joyce Palla on the Board.

### **Dr Debbie Mack, PD, Board Member, Bentonville, AR**

Governor Hutchinson appointed **Dr Debbie Mack** to the Board in May 2016.

Dr Mack received her bachelor of science degree in pharmacy from the University of Texas at Austin College of Pharmacy. She holds an active pharmacist license in both Texas and Arkansas.

Dr Mack served as a community pharmacist in Texas for her family-owned independent pharmacy. In 1988, she joined Walmart Pharmacy as a staff pharmacist and served in multiple areas of pharmacy operations, including pharmacy manager, district manager, operations coordinator, regional manager, and divisional manager. In Dr Mack's current role as the senior director, practice compliance, she ensures corporate compliance with regulatory requirements and state legislative changes for Walmart Pharmacy in 17 states, including Arkansas. In 2015, Walmart honored Dr Mack with the Buzz Cruickshank Leadership Award for setting the example in leadership for Walmart Health and Wellness.



In addition to serving on the Board, Dr Mack is currently the president-elect of the Texas Federation of Drug Stores. This role allows her a seat on the Texas Pharmacy Congress and the Texas Pharmacy Summit. She is an active member of the Arkansas Pharmacists Association and serves on the Professional Affairs & Ethical Practices Committee. Dr Mack is a member of the American Society for Pharmacy Law and serves on the education committee. In addition, Dr Mack has professional memberships in the Texas Pharmacy Association and the American Pharmacists Association. Dr Mack served as a member of the National Association of Boards of Pharmacy® (NABP®) steering committee for community pharmacy accreditation. She maintains her certification in health care compliance and is a certified compliance and ethics professional. Dr Mack and her husband, Gary, have two sons, Cody and Wesley, and three grandchildren.

Dr Mack is replacing Dr Cheryl Bryant on the Board.

### **'What to Expect When We Are Inspecting'**

The Board recently introduced a new CE topic during the Arkansas Pharmacists Association Annual Convention, titled "What to Expect When We Are Inspecting." While that title seems obvious, the Board really is trying to help pharmacists identify some issues that are commonly seen so that they can be reviewed throughout the year in preparation for inspection. An immediate tip for anyone would be to periodically review your last inspection to see if you think you are prepared for the next one. Some of the most

common deficiencies seen in 2015 based on one inspector's experience include:

- ◆ Hydrocodone not counted in October 2014 for Schedule II inventory – 17.3%
- ◆ Need to add exempt products to control counts (codeine, pseudoephedrine (PSE), ephedrine) – 15.7%
- ◆ Unable to locate CS inventory – 7.3%
- ◆ CS inventory did not include all required information – 6.3%
- ◆ Pharmacist signature log insufficient – 6.3%
- ◆ Unable to locate technician policy and procedure for order entry – 4.3%
- ◆ Repackaged medications with expiration date of greater than 12 months – 4%
- ◆ No PSE sales until scanner in use – 3.7%
- ◆ Food and Drug Administration statements not included with prescriptions – 3.3%

### **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 can be utilized for retail customers, assisted living, and jails/prisons once the agreement is signed. If you need an MOU for multi-dose packaging, please contact the Board office or download the MOU from the Forms and Instructions section on the Board website. As an additional reminder, pharmacies may not take back multi-dose packaging systems to be repackaged a second time for customers or patients.

### **Prescription Drug Take-Back Success Ongoing and ARTakeBack.org**

The April 2016 Arkansas drug take-back event resulted in a total of 25,289 pounds of unused medications being gathered, which once again surpassed the Board's hopes for this event and also shows why Arkansas is ranked third in the nation for drug take-back. The cumulative efforts of the Board's take-back events have resulted in 187,702 pounds of unused medications being removed from homes and destroyed responsibly so that they can no longer be a risk to someone else. (See Figure A on page 5 of this *Newsletter*.) This fact is astounding when considering that without this service, millions of doses 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 previous State Drug Director Fran Flener on the [www.ARTakeBack.org](http://www.ARTakeBack.org) website that has been and will continue to be updated with information about drug disposal and destruction. The next DEA National Prescription Drug Take-Back Day event will take place on October 22, 2016.

### **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*.

**Figure A. Medication Take-Backs 2010-2016**

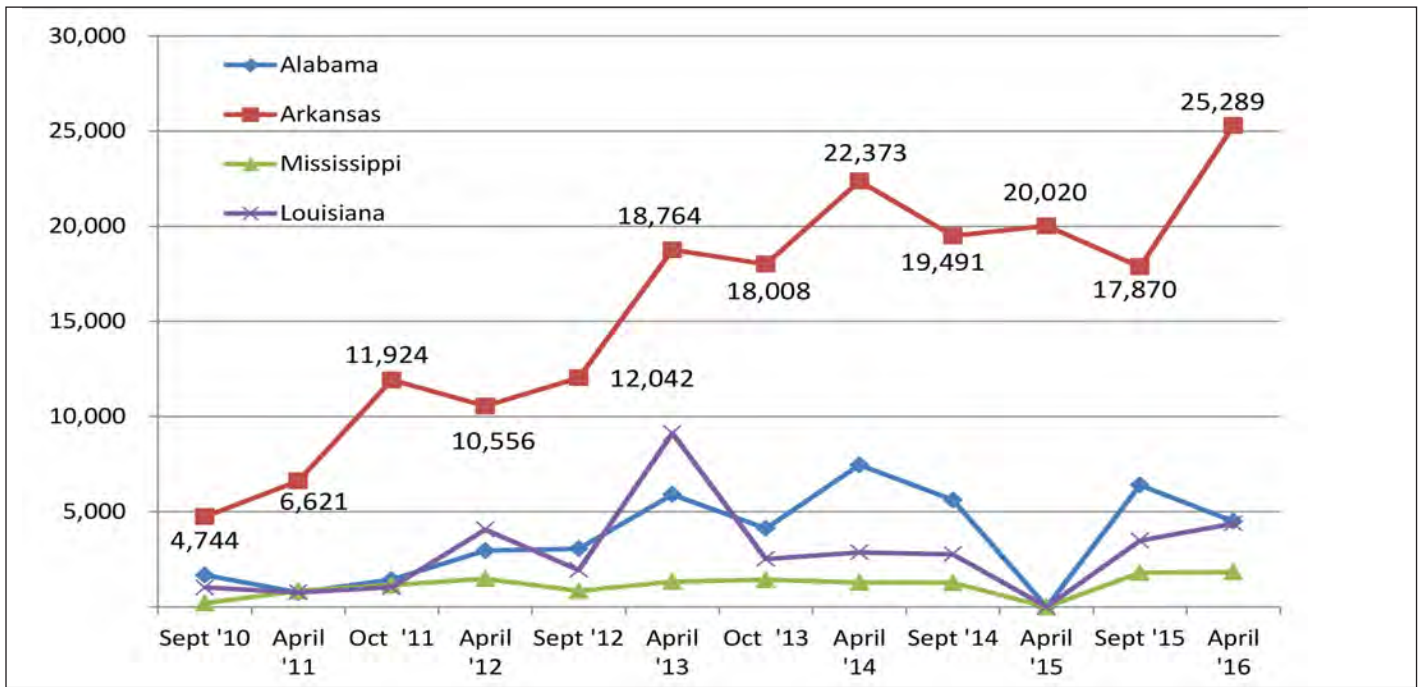


Figure A shows medication taken back and destroyed per event compared to other states in Arkansas' DEA region. Please note, a DEA National Prescription Drug Take-Back Day was not held in April 2015; however, Arkansas held a statewide take-back at that time.

**Fred T. Mahaffey Award: Arkansas State Board of Pharmacy**

For their contributions to the regulation of the practice of pharmacy and their efforts to combat prescription drug abuse, the members of the Arkansas State Board of Pharmacy received the 2016 Fred T. Mahaffey Award from NABP. The Board has partnered with several organizations, such as consumer groups and law enforcement agencies, to develop a multifaceted campaign to address prescription drug abuse in Arkansas. Such efforts include a public service announcement featuring the state governor urging the use of over 100 take-back receptacles around the state. Each year, the Board also sponsors the Arkansas Prescription Drug Abuse Summit, an event that provides the opportunity for health care professionals to gain CE during a day-long conference focused on the abuse of and addiction to prescription drugs. The summit is funded through government and noncommercial interests, resulting in free registration and accredited CE offerings. In 2015, the Board's partnerships with the Arkansas National Guard and several law enforcement agencies resulted in more than 37,000 pounds of drugs being removed from homes and destroyed responsibly to prevent abuse and misuse.

**Arkansas Pharmacists Association Honors John Clay Kirtley With Award**

John Clay Kirtley, PharmD, Board executive director, was presented with the 2016 Cardinal Health Generation Rx Award at the Arkansas Pharmacists Association Annual Convention in June. This award honors a pharmacist who has demonstrated outstanding commitment to raising awareness of the dangers of prescription drug abuse among the general public and among the pharmacy community. The

award is also intended to encourage educational prevention efforts aimed at patients, youth, and other members of the community. John was quoted as saying:

Winning this award is quite humbling. Since I was in pharmacy school, I have taken a focus on prescription drug misuse and addictive disease. During my tenure with the Board of Pharmacy, I believe that we have really taken an expanded educational approach to partner with other interested parties to show a couple of things in this area: First, this is an 'us' issue, not a 'them' issue. With roughly 400 drug overdose deaths in Arkansas each year, drug misuse, abuse, and the disease of addiction affect all of [us] in some way. Secondly, in recognizing that addiction is a disease, you must also recognize that it is treatable and that we must all work together in order to solve the epidemic we are facing with prescription drugs.

**Arkansas Pharmacy Support Group Help Line  
870/636-0923**