May 2019

Arkansas State Board of Pharmacy News

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Legislative Updates From 2017

Act 284 – An Act to Amend the Provisions of Arkansas Code Concerning the Practice of Pharmacy; to Authorize Use of Pharmacists to Provide Access to and Administration of Certain Medications; to Authorize Dispensing of Certain Medication by Physicians; And for Other Purposes

This act, sponsored by Senators Cecile Bledsoe and Lance Eads as well as Representative Justin Boyd, erases the limited list of medications that a pharmacist can administer and instead points to the Arkansas State Board of Pharmacy to make rules on any limits. Previous language limited pharmacists to administering immunizations, vaccines, allergy medications, vitamins, minerals, antihyperglycemics, and anti-nausea medications. Added language allows pharmacists to initiate therapy and administer and/or dispense naloxone pursuant to a statewide protocol. This act also allows physicians to dispense naloxone or contraceptives without a dispensing permit. More detailed information, including the protocol, may be found on the Board's website at *https://www.pharmacyboard.arkansas.gov/naloxone.*

Act 477 – An Act to Amend Laws Regarding the Practice of Pharmacy and the Arkansas State Board of Pharmacy; and for Other Purposes

This act, sponsored by Representatives Jimmy Gazaway and Justin Boyd as well as Senator David Sanders, addresses seven specific areas of the regulation of the practice of pharmacy by:

1. Clarifying that Board inspectors/investigators can seize products to test for sterility, potency, and pyrogenicity when inspecting permitted facilities.
2. Deleting the word "gross" from the terminology "gross unprofessional conduct" as there is no differentiation for "gross" and Board rules only define unprofessional conduct.
3. Matching the Board's fining authority to other health care licensure boards at $1,000 per incident rather than $500. (The Board has seldom fined the maximum amount currently, but there are times when it has been needed as an alternative to closing a business and causing patient disruption.)
4. Allowing the Board to assess a monetary penalty in addition to revoking a permit when appropriate.
5. Allowing the Board to recoup investigative costs incurred when preparing for and holding a disciplinary hearing.
6. Allowing the Board to collect costs of inspections when it needs to inspect an out-of-state facility permitted with the Board.
7. Updating notification requirements so that they match the Board's rules to give five days for certain notifications versus the three days reflected by previous statutes.

Act 139 – An Act to Amend the Comprehensive Criminal Record Sealing Act of 2013 to Allow a State Agency or Board Engaged in the Licensing of Medical Professionals to Have Access to and use of Expunged and Sealed Records of Criminal Convictions; and for Other Purposes

This act, sponsored by Representative Justin Boyd and Senator Missy Irvin, clarifies that health licensure boards have the ability to view and consider sealed convictions when considering licensing of applicants.

Act 401 – An Act to Make an Appropriation for Pharmacy Student Loans and Scholarships for the State Board of Pharmacy for the Fiscal Year Ending June 30, 2018; and for Other Purposes

This act, sponsored by Representative Les Eaves, allows the Board to establish a second rural loan/scholarship program in Arkansas with funding of $275,000. This loan/scholarship program will be similar to the

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National Pharmacy Compliance News

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NABPF
National Association of Boards of Pharmacy Foundation

The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

FDA Launches Pilot Program to Improve Security of Drug Supply Chain With an Innovative Approach

Food and Drug Administration (FDA) has launched a pilot program allowing participants representing the various parts of the drug supply chain to pilot innovative and emerging approaches for enhanced tracing and verification of prescription drugs in the United States' supply chain. The program is in line with FDA's ongoing efforts to prevent suspect and illegitimate products from entering the supply chain, according to an FDA press release. Eligible manufacturers, repackagers, and other stakeholders can apply to participate in the program, which will inform the development of the enhanced electronic, interoperable track-and-trace system for industry set to go into effect in 2023 in accordance with the Drug Supply Chain Security Act (DSCSA), enacted by Congress on November 27, 2013.

The pilot technologies of this program may become part of FDA's enhanced expectations for reliable track-and-trace systems, which will be designed to reduce diversion of drugs distributed domestically and to keep counterfeit drugs from entering the supply chain. The DSCSA pilot project program is intended to help identify and evaluate the most efficient processes to comply with and apply drug supply chain security requirements and will aid in identifying attributes the system will need for enhanced product tracing and verification, as well as electronic means to share the information. FDA recently issued draft guidance on the use of product identifiers with a unique serial number to improve verification down to the package level. FDA has also provided draft guidance for verification systems to quarantine and investigate suspect and illegitimate drugs.

Additional information on the FDA pilot program is available in a February 8, 2019 announcement in the *Federal Register.*

FDA Announces New Efforts to Increase Oversight and Strengthen Regulation of Dietary Supplements

Noting that three in four Americans now take at least one dietary supplement on a regular basis, and that the dietary supplement industry has expanded to include as many as 80,000 different products for consumers, FDA Commissioner Scott Gottlieb, MD, has announced new plans to increase the agency's oversight of dietary supplements. These initiatives include communicating to the public as soon as possible when there is a concern about a dietary supplement on the market, ensuring that the regulatory framework is flexible enough to adequately evaluate product safety, and continuing to work closely with industry partners. FDA is also developing new enforcement strategies to respond to entities that violate standards established under the Dietary Supplement Health and Education Act of 1994.

On February 11, 2019, FDA sent 12 warning letters and five online advisory letters to foreign and domestic companies that are illegally selling more than 58 products. The products are illegally marketed as unapproved new drugs that make unproven claims about preventing, treating, or curing Alzheimer's disease, as well as a number of other serious diseases and health conditions, such as diabetes and cancer. In his statement, Gottlieb noted that most stakeholders in the industry act responsibly, but he expressed concern over the ability of bad actors to exploit the system by providing potentially dangerous products and making unproven or misleading claims about the health benefits supplements may offer.

FDA is planning a public meeting on this topic during the second quarter of 2019. For more information, view the FDA statement at *https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm631065.htm.*

Trump Administration Releases National Drug Control Strategy to Reduce Drug Trafficking and Abuse

As the opioid crisis continues to claim the lives of tens of thousands of Americans each year, the Office of National Drug Control Policy has released its *National Drug Control Strategy.* The *Strategy* breaks down the administration's priorities in addressing the crisis, with an emphasis on three areas: prevention, treatment and recovery, and reducing availability.

- **Prevention** efforts are focused on educating both consumers and caregivers about the dangers of opioid misuse and include a new national media campaign, continued efforts to expand prescription monitoring programs (PMPs), and improving the ability of state, local, and tribal communities to identify and prevent substance abuse.
- **Treatment and recovery recommendations** in the *Strategy* include improving access to naloxone, improving evidence-based addiction treatment, and eliminating barriers for accessing treatment.

- **Reducing availability** strategies are focused on disrupting illegal supply chains, defeating drug traffickers, increased cooperation with international partners, and combating illegal internet drug sales.

The document notes that the "most important criterion of success" is saving lives and calls for the federal government to work closely with state and local governments, as well as other stakeholders. Additional information, including the full strategy document, is available on the White House website at *https://www.whitehouse.gov/opioids.*

National Association of Boards of Pharmacy® (NABP®) and its member boards of pharmacy remain committed to advancing best practices for PMPs in the interest of public health. NABP's PMP data sharing system, NABP PMP InterConnect®, facilitates the secure transfer of PMP data across state lines and provides an effective means of combating drug diversion and drug abuse nationwide. In addition, NABP and its member boards continue efforts to educate consumers about prescription drug safety. The NABP AWAR$_X$E® Prescription Drug Safety Program's Drug Disposal Locator Tool has more than 6,000 disposal locations and continues to add new locations to provide consumers with a safe way to dispose of medication and help prevent misuse and abuse of prescription medications. For more information about PMP InterConnect and the AWAR$_X$E program, visit the Initiatives section of the NABP website at *www.nabp.pharmacy.*

New Study Predicts Opioid Epidemic Will Worsen Over the Next Decade

More than 700,000 people will die from opioid overdoses between 2016 and 2025, and annual overdose deaths will reach nearly 82,000 by 2025, estimates a new study published to *JAMA Network Open.* The estimate is based on an analysis of data from the National Survey on Drug Use and Health and the Centers for Disease Control and Prevention from 2002 to 2015.

Researchers also projected that intervention efforts focused on lowering the incidence of prescription opioid misuse would help to reduce the number of deaths 3.8% to 5.3%, a figure the researchers described as "modest," due to the changing nature of the opioid crisis. The study notes that more people are directly initiating opioid use with illicit opioids rather than prescription drugs, and illicit opioids have become more lethal with the availability of illegally manufactured fentanyl.

The researchers encourage policymakers to take "a stronger and multipronged approach" to reduce the impact of the ongoing opioid overdose epidemic. The full article is available at *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2723405.*

FDA Warns of Potential Blood Pressure Medication Shortages Due to Recalls

FDA is warning health care providers and consumers of a shortage of angiotensin II receptor blockers, commonly used to treat high blood pressure. A growing list of medications containing valsartan, losartan, and irbesartan have been recalled from the market for containing an impurity that may present a cancer risk to patients. The issue was first detected in the summer of 2018, according to a statement posted to the FDA website. Since then, FDA has placed a Chinese manufacturer of the active ingredient on import alert to stop their imports, and FDA is working with other manufacturers to recall affected medications.

In the statement, FDA notes that the risk to individual patients remains very small, but that there is still reason to be concerned about the potential health risks. Medications with these impurities are believed to have been in the market for about four years.

"Now that these risks are identified, we're applying what we've learned to the evaluation of similar manufacturing processes where we now know these risks could arise," the statement notes. The FDA press release is available at *https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm629796.htm.*

FDA Releases Two Draft Guidances Related to REMS Programs

FDA has released two new draft guidances to ensure risk mitigation programs put in place for certain drugs and biologics, as required for approval, are working. The agency's primary risk management tool is FDA-approved product labeling. However, in limited cases, FDA may require a Risk Evaluation and Mitigation Strategy (REMS) to help ensure a drug's benefits outweigh its risks.

The following guidances relate to the assessment of REMS programs:

- **REMS Assessment: Planning and Reporting Guidance for Industry** describes how to develop a REMS Assessment Plan.
- **Survey Methodologies to Assess REMS Goals That Relate to Knowledge Guidance for Industry** provides recommendations on conducting REMS assessment surveys to evaluate patient or health care provider knowledge of REMS-related information.

FDA states that the goal in providing this guidance for REMS is to ensure constant improvement of their safety programs and establish the most efficient and effective programs moving forward, to optimize patient care and keep consumers safe and healthy. More information on REMS is available on the FDA website at *https://www.fda.gov/drugs/drugsafety/rems.*

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current program that has been funded by the Board at the University of Arkansas for Medical Sciences College of Pharmacy with $900,000 over the last eight years. This money has been used to assist junior and senior pharmacy students who plan to return to rural Arkansas to practice after graduation. If the students receiving the loans return to full-time practice for three years (36 consecutive months) in a qualified rural setting (defined as a location with a population of 15,000 or less, located at least 15 miles from the nearest incorporated municipality with 50,000 or more inhabitants according to the census), then the loans become scholarships and do not have to be repaid. It is important to note that the Board does not anticipate any increases in fees due to these loan/scholarship programs and it has in fact not had a fee increase since the 1990s.

Act 282 of 2017 – An Act to Modify the Emergency Refill of Prescription by Pharmacists; and for Other Purposes

This act, sponsored by Senator Lance Eads and Representative Clint Penzo, removes the restriction by statute that limits emergency prescription refills to a 72-hour supply.

Act 820 of 2017 – An Act to Amend the Prescription Drug Monitoring Program to Mandate Prescribers Check the Prescription Drug Monitoring Program When Prescribing Certain Medications; and for Other Purposes

This act, sponsored by Senator Jeremy Hutchinson and Representative Kim Hammer, accomplishes the following:

- States that a practitioner must access the prescription drug monitoring program (PDMP):
  - Each time a Schedule II or III opioid is prescribed
  - The first time a benzodiazepine is prescribed
- Exempts practitioners from accessing the PDMP:
  - Immediately before or during surgery
  - During surgery recovery in a health care facility
  - In a health care facility
  - During an emergency situation at the scene of an emergency and in a licensed ground ambulance, air ambulance, or the intensive care unit of a licensed hospital
  - For palliative care or hospice patient
  - For residents in a licensed nursing home facility
  - In situations where the PDMP is not accessible due to technological or electrical failure
- Requires licensed oncologists to check for initial malignant episodic diagnosis and every three months thereafter while continuing treatment
- Allows Arkansas Department of Health (ADH) to send quarterly reports to prescribers and dispensers; and if information still looks suspect after 12 months, ADH can report it to the licensing boards
- Pushes for same-day and even real-time reporting
- Expands the PDMP oversight board with a representative from the medical board and the dental board
- Can allow for exemptions to the law through ADH with legislative approval
- Allows licensure boards to adopt rules limiting the quantities of medications that can be prescribed or dispensed

Authorized Generics

The Board recently discussed the fact that many "generics" are not equivalently rated due to the fact that they are actually classified as a Food and Drug Administration (FDA)-"authorized generic" rather than a generic drug. So, what does that mean? The following explanation is taken from the FDA web page, *https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/abbreviatednewdrugapplicationandagenerics/ucm126389.htm.*

Is an Authorized Generic Drug the Same Thing as a Generic Drug?

No. The term "authorized generic" drug is most commonly used to describe an approved brand name drug that is marketed without the brand name on its label. Other than the fact that it does not have the brand name on its label, it is the exact same drug product as the branded product. An authorized generic may be marketed by the brand name drug company, or another company with the brand company's permission. In some cases, even though it is the same as the brand name product, a company may choose to sell the authorized generic at a lower cost than the brand name drug.

The more important question is, "What does that mean for pharmacists in Arkansas?" The Board discussed this issue and, as a matter of policy, the Board clarified that substitution of an FDA-authorized generic is accepted by the Board due to the fact that even the manufacturer is declaring that it is the same drug with a different label, which prevents the drug from having an equivalent rating that would match up like a normal generic drug. To make a long story short: Authorized generics may be automatically substituted for their branded counterparts.

Changes to Schedule II Prescriptions

The majority of changes to a Schedule II prescription can be made only after the pharmacist contacts the prescribing practitioner. After consulting with the prescriber, the pharmacist is permitted to change the patient's address, drug strength, drug quantity, drug dosage form, and directions for use. The pharmacist may add information such as the patient's address or the physician's Drug Enforcement Administration (DEA) number. The pharmacist is never permitted to make changes to the patient's name, controlled substance (CS) prescribed (except to substitute a generic), or the prescriber's signature. Also, the date of the original prescription may not be changed. However, after consulting directly with the prescriber, directions to fill after a certain date may be changed. The pharmacist must document any changes made, the time and date when the change was made, and provide his or her signature. Documentation on the prescription is the pharmacist's account of the changes made. These changes should match what appears in the patient's chart at the prescriber's practice site if the dosage form or the directions for use are changed.

Receipt of Scheduled Drug Orders

When a purchaser receives a shipment of CS, the purchaser must record the date that the CS is actually received on the invoice and verify the quantity of each item received. Documenting the verification by signing the invoice is highly recommended. The DEA Form 222 must also be completed with the actual quantity received and the date received.

Pharmacist-to-Pharmacy Technician Ratio

Each pharmacist on duty may utilize three pharmacy technicians to assist the pharmacist in his or her duties. Technicians must be under direct supervision of the pharmacist and the tasks performed by them must be checked and approved by the supervising pharmacist. The supervising pharmacist is responsible for all tasks performed by the pharmacy technician. Technician duties are detailed in Board Regulation 03-00-0005.

Supportive personnel are not included in the one-to-three ratio. Supportive personnel functions are those not related to the preparation or distribution of medication, such as clerks, secretaries, messengers, and delivery personnel.

This ratio is the same regardless of the setting (hospital, retail, or specialty). A pharmacist may supervise no more than one student intern in addition to three pharmacy technicians. Graduate interns do not affect the ratio.

Pharmacies utilizing pharmacy technicians must also have policies and procedures delineating technician duties and restrictions as well as a description of the process whereby a supervising pharmacist verifies the pharmacy technician's tasks.

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.*

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