May 2019

News

Alabama State Board of Pharmacy

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Changes to Alabama Pharmacy Laws

The Alabama State Board of Pharmacy has been working diligently with its partners in this state to pass legislation that will impact the practice of pharmacy and improve health care for the citizens of Alabama. Thank you to the Alabama Pharmacy Association, the Alabama Society of Health-System Pharmacists, Auburn University's Harrison School of Pharmacy, and Samford University's McWhorter School of Pharmacy for their dedication and drive. Letters and phone calls from Alabama pharmacists have been an integral part of working to have important legislation passed. Thank you to all the pharmacists who took the time to promote pharmacists' ability to impact patient outcomes. The Board is hopeful that this legislative session will provide for an expansion of pharmacists' role in disease-state management and overall improvement in patient outcomes in Alabama.

In addition to identifying and implementing any needed changes to the Alabama Pharmacy Practice Act, the Board continuously reviews current rules for applicability and cause for enforcement. In the past several months, the Board has implemented the following changes to Alabama State Board of Pharmacy Administrative Code **(emphasis added).**

680-X-2-.12 – Supervising Pharmacist

(6) If the actions of the permit holder have deemed to contribute to or cause a violation of any provision of this section, the Board may hold the permit holder responsible and/or absolve the supervising pharmacist from the responsibility of that action. **In addition, it is a violation of this rule for any person to subvert the authority of the supervising pharmacist by impeding the management of any pharmacy in relation to compliance with federal and state drug or pharmacy laws and regulations. Any such act(s) may result in charges being filed against the permit holder.**

The role of the supervising pharmacist is vital in ensuring accountability for the safe practice of pharmacy. The Board too often hears from supervising pharmacists that in their role, the supervising pharmacist does not have the authority to ensure proper adherence to state and federal regulations due to influences outside of the pharmacy. This rule change was made expressly to reinforce the authoritative position of the supervising pharmacist when the permit holder (who is not the supervising pharmacist) is advising/advocating/pressuring a supervising pharmacist to act or allow the pharmacy to act in any way that is outside of legal parameters. The supervising pharmacist of record is the responsible party for all activities of the pharmacy and its staff.

680-X-2-.36 – Continuing Education for Pharmacists

(5) The Board of Pharmacy shall randomly audit the continuing education documentation or information to be maintained or submitted by each pharmacist as described herein to assure compliance with these rules. Failure to maintain the documentation or information set forth in these rules or the submission of false or misleading information or documentation to the Board of Pharmacy or failure to submit requested documentation or information within the time specified by the Board may subject the pharmacist, **on the first violation to a non-disciplinary administrative penalty authorized Code of Ala. 1975, §34-23-33(b) an amount not less than one hundred dollars ($100.00) or more than two hundred fifty dollars ($250.00) as determined by the board.**

680-X-2-.37 – Continuing Education for Pharmacy Technicians

(5) The Board of Pharmacy shall randomly audit the continuing education documentation or information to be maintained or submitted by

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National Pharmacy Compliance News

May 2019

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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each pharmacy technician as described herein to assure compliance with these rules. Failure to maintain the documentation or information set forth in these rules or the submission of false or misleading information or documentation to the Board of Pharmacy or failure to submit requested documentation or information within the time specified by the Board may subject the pharmacy technician, **on the first violation to a non-disciplinary administrative penalty authorized Code of Ala. 1975, §34-23-132 an amount not less than twenty five dollars ($25.00) or more than one hundred dollars ($100.00) as determined by the board.**

The Board is charged with ensuring public safety, which entails enforcing Alabama statutes and rules. To that end, the Board audits pharmacists and technicians for compliance with continuing education (CE) requirements, after the renewal cycle for licenses and permits. Changes to 680-X-2-.36 and 680-X-2-.37 allow for a pharmacist or technician to have a one-time failure to achieve compliance in the designated time period without this failure resulting in an administrative sanction on the individual's license or registration, which would require mandatory reporting to the National Practitioner Data Bank. This **does not** change the requirement to complete the CE for the specified time frame. CE is intended to expand a practitioner's foundation of information and stay abreast of the advances in health care. As practitioners continue to grow their impact on patient outcomes, it is more important than ever that all practitioners remain highly informed of new protocols and drug therapies.

While continuing the charge of enforcing statutes and rules, the Board has identified a trend in practitioners failing to notify the Board of changes in employment and/or position. In practice, this means that any time a pharmacist changes job description from supervising pharmacist to staff pharmacist, and vice versa, the pharmacist must report that change to the Board within 10 days of the change, per 680-X-2-.12(2). In addition, whenever a pharmacist, intern, extern, or technician changes physical location of employment, then the pharmacist, intern, extern, or technician must report that change to the Board within 10 days of the change, per 680-X-2-.10. Please ensure that as a practitioner, you are compliant with this rule. It is not sufficient to provide updates only during the renewal cycle.

New Board Policies

The Board has recently approved two new policies, 18-011: Refill Authorizations Reduced to Writing and 19-002: Prescription Acceptance Reduced to Writing.

Board Policy 18-011: Refill Authorizations Reduced to Writing

If the pharmacy uses a fax refill authorization form and puts all the required information on the prescription, whether it's handwritten or computer generated, it is a valid prescription. If assigned a new prescription number, it is considered by the Alabama Board of Pharmacy to be reduced to writing.

This policy was adopted by the Board during its business meeting on September 19, 2018, and approved by all Board members.

Board Policy 19-002: Prescription Acceptance Reduced to Writing

If the pharmacist or registered intern accepts an oral prescription of any nature, the pharmacist or registered intern may directly enter the information into an electronic system. This process of keying the information immediately into a pharmacy system will be considered "reduced to writing" by the Alabama Board of Pharmacy.

This policy was adopted by the Board during its business meeting February 20, 2019, and approved by all Board members.

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