November 2019

News

# Alabama State Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

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## *Pharmacist Oversight Responsibility*

Over the past several months, the Alabama State Board of Pharmacy has received numerous complaints from pharmacists related to technician ratio and workload.

The Board is charged with upholding the Alabama Practice of Pharmacy Act and the rules that apply. With respect to the complaints that have been received, the Board wants to make all pharmacists and technicians very aware of their responsibilities.

### 680-X-2-.12 Supervising Pharmacist

Before assuming the responsibility of a supervising pharmacist, a pharmacist should read and ensure a complete understanding of this rule. For those already serving as a supervising pharmacist, it is prudent to make sure you are aware of the responsibilities imposed upon you by this rule.

Section (4)(i) states that the supervising pharmacist shall be responsible for "[e]nsuring compliance with the provisions for the Pharmacy Practice Act, Rules of the Alabama State Board of Pharmacy and the Controlled Substances Act."

Section (6) states, ". . . 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."

As a practicing pharmacist, you are responsible for your professional practice. As a supervising pharmacist, you are responsible for every action and/or practice occurring within the pharmacy that you are supervising. The role of the supervising pharmacist is not just a title. The Board places a great deal of accountability on the professional who agrees to assume that responsibility. As such, any pharmacist taking on this role should be careful to educate all staff of the statutes and rules governing their particular practice setting. The supervising pharmacist should observe, verify, and address actions to ensure compliance with state regulations. Any violations for the pharmacy may be held as violations of the supervising pharmacist and in most instances, the pharmacist on duty when an offense occurs, in addition to the supervising pharmacist.

### 680-X-2-.14 The Role of Technicians in Alabama

This rule is currently under review for revision to remove the "Alabama" stipulation. If approved, the rules would more clearly define the Board's view that all pharmacies, within or outside of Alabama, should follow the same rules for technician oversight.

Section (3) states, "It is ruled by the Board of Pharmacy that three (3) technicians, one of which shall be certified by any credentialing organization approved by the Board, on duty are sufficient in the prescription area of a retail pharmacy or an institutional pharmacy for each full time licensed pharmacist on duty. Nothing in this rule shall prevent a pharmacy from employing technicians to perform supervised tasks not requiring professional judgment."

It should not be surprising, based on the earlier rule, that the Board expects all pharmacists, with emphasis on the supervising pharmacist, to uphold the three technicians (including one who is certified) to one pharmacist ratio.

The Board is receiving numerous complaints of facilities operating outside the 3:1 ratio. Please be mindful that as a pharmacist, if you are working in an environment where the ratio is being abused, you may be at risk of disciplinary action on your license.

### 680-X-2-.22 Code of Professional Conduct

Section(2)(d) states, "A pharmacist has the duty to observe the law, to uphold the dignity and honor of the profession, and to accept its ethical principles. A pharmacist and a pharmacy should not engage in any activity that will bring discredit to the profession and should expose, without fear or favor, illegal or unethical conduct in the profession."

Simply stated, all pharmacists must do what is required to ensure that no matter what the circumstance or working environment, the pharmacist is diligently engaged in following statutes and rules and conducting himself or herself in a moral and ethical manner. It is important to recognize

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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.


## USP Postpones Official Dates of USP General Chapters Revisions and Additions

United States Pharmacopeial Convention (USP) has announced that the effective date of the following changes to USP general chapters will be postponed:

- General Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations
- General Chapter <797> Pharmaceutical Compounding – Sterile Preparations
- General Chapter <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging

The delay is in accordance with USP's Bylaws, which require the official date of the standard to be postponed while an appeal is pending. In the meantime, conformance with the official versions of Chapters <795> and <797>, including the section "Radiopharmaceuticals as CSPs," will remain official, according to a notice posted to the USP website.

Revisions to USP General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings are not subject to pending appeals, and will become official on December 1, 2019. During this interim period, Chapter <800> is "informational and not compendially applicable," according to the USP notice. However, the organization encourages utilization of the chapter in the interest of advancing public health. USP also notes that it plays no role in enforcement and that regulators continue to have the authority to make their own determinations regarding enforceability of Chapter <800>.

## FDA Issues Statement on Compounded Bulk Drug Substances Ruling

A US district court judge in Washington, DC, recently upheld Food and Drug Administration's (FDA's) interpretation of clinical need regarding bulk substances that may be used by outsourcing facilities in drug compounding. In response to the ruling, FDA has released a statement commending the decision as a "victory for public health in the first such case since the Drug Quality and Security Act (DQSA) was enacted."

In March 2019, FDA announced that vasopressin would not be included as an approved bulk drug substance because there is already an approved product on the market to meet the same medical needs. The ruling was in response to a challenge of that interpretation. In their statement, the agency states that they will continue to evaluate bulk drug substances nominated for use in compounding by outsourcing facilities using the same interpretation of clinical need.

"Our compounding work remains a top priority at the agency. We've long recognized that compounded drugs can serve an important role for patients whose medical needs cannot be met by an FDA-approved drug product," the agency states. "But compounded drugs are not approved by the FDA and, therefore, have not been evaluated for safety, efficacy or quality. We've seen first-hand the harm they can cause patients when they're not appropriately compounded."

## HHS, FDA Publish New Action Plan for Importation of Certain Prescription Drugs

The US Department of Health and Human Services (HHS) and FDA have published a Safe Importation Action Plan to allow for the safe importation of certain drugs originally intended for foreign markets. The action plan outlines two possible pathways:

- **Pathway 1** would rely on the authority in the Federal Food, Drug, and Cosmetic Act Section 804 to authorize demonstration projects to allow importation of drugs from Canada. The proposed rules would include conditions to ensure the importation poses no additional risk to consumers and must result in a significant cost reduction.
- **Pathway 2** would allow manufacturers to import versions of FDA-approved drug products that they sell in foreign countries that are the same as the US versions. Manufacturers would use a new National Drug Code for those products, potentially allowing them to offer a lower price than what their current distribution contracts require.

The action plan states that the final proposal for these rules may differ from the descriptions "to reflect further consideration of the relevant issues."

"Today's proposal is the result of the hard work by the dedicated staff of the FDA, in close collaboration with HHS and the White House, to identify potential pathways we can pursue to support the safe importation of certain prescription drugs," said Acting FDA Commissioner Ned Sharpless, MD in a press release. "We've been keenly focused on ensuring the importation approaches we've outlined pose no additional risk to the public's health and safety. We know there are many operational challenges to address through each of these pathways, and are actively working through them as we look to formally announce these policies, with opportunity for public comment, in the coming months."

The full action plan can be accessed via the HHS website at *https://www.hhs.gov/sites/default/files/safe-importation-action-plan.pdf.*

## Pain Reliever Misuse Decreased by 11% in 2018, NSDUH Survey Indicates

Prescription drug misuse, including abuse of stimulants and pain relievers, decreased in 2018, according to the recently released 2018 National Survey on Drug Use and

Health (NSDUH). The annual survey, conducted by the Substance Abuse and Mental Health Services Administration (SAMHSA), a division of HHS, is a primary resource for data on mental health and substance use, including abuse of prescription drugs, among Americans.

Key findings of the 2018 NSDUH include:

- Past-year abuse of psycotherapeutics decreased from 6.6 from 6.2%.
- Past-year abuse of pain relievers decreased from 4.1% to 3.6%.
- Past-year abuse of stimulants decreased from 2.1% to 1.9%.
- Past-year abuse of opioids decreased from 4.2% to 3.7%.

"This year's National Survey on Drug Use and Health contains very encouraging news: The number of Americans misusing pain relievers dropped substantially, and fewer young adults are abusing heroin and other substances," said HHS Secretary Alex Azar. "At the same time, many challenges remain, with millions of Americans not receiving treatment they need for substance abuse and mental illness. Connecting Americans to evidence-based treatment, grounded in the best science we have, is and will remain a priority for President Donald Trump, for HHS, and for SAMHSA under Assistant Secretary Elinore McCance-Katz."

A recorded presentation of the data, along with a written summary and the full report are available on the SAMHSA website at *https://www.samhsa.gov/data/nsduh/reports-detailed-tables-2018-NSDUH.*

## Additional Efforts Needed to Improve Naloxone Access, CDC Says

A new Vital Signs report published by the Centers for Disease Control and Prevention (CDC) states that naloxone dispensing has grown dramatically since 2012, with rates of naloxone prescriptions dispensed more than doubling from 2017 to 2018 alone. However, the rate of naloxone dispensed per high-dose opioid dispensed remains low, with just one naloxone prescription dispensed for every 69 high-dose opioid prescriptions.

The researchers for the report examined dispensing data from IQVIA, a health care, data science, and technology company that maintains information on prescriptions from 50,400 retail pharmacies, representing 92% of all prescriptions in the US. According to their analysis, dispensing rates were higher for female recipients than for male recipients, and higher for persons aged 60-64 years than for any other age group. The researchers also found that the rate of naloxone prescriptions dispensed varied substantially across US counties, with rural and micropolitan counties more likely to have a low-dispensing rate.

"Comprehensively addressing the opioid overdose epidemic will require efforts to improve naloxone access and distribution in tandem with efforts to prevent initiation of opioid misuse, improve opioid prescribing, implement harm reduction strategies, promote linkage to medications for opioid use disorder treatment, and enhance public health and public safety partnerships," the report states in its conclusion. "Distribution of naloxone is a critical component of the public health response to the opioid overdose epidemic."

The Vital Signs report can be accessed at *www.cdc.gov/mmwr/volumes/68/wr/mm6831e1.htm.*

## Altaire Pharmaceuticals Recalls Multiple OTC Ophthalmic Products

Due to a lack of sterility assurance, Altaire Pharmaceuticals, Inc, is voluntarily recalling over-the-counter (OTC) drug products and lots sold as generic ophthalmic medications at Walgreens, Walmart, CVS, and other retail pharmacies. To date, there have been no reports of adverse events related to the recalled products.

A full list of the affected products and lot numbers, as well as instructions on how to return the product, are available through the following press releases:

- Altaire Pharmaceuticals, Inc. Issues Voluntary Recall Of Multiple Ophthalmic Products Sold At CVS
- Altaire Pharmaceuticals, Inc. Issues Voluntary Recall of Multiple Ophthalmic Products Sold at Wal Mart
- Altaire Pharmaceuticals, Inc. Issues Voluntary Recall of Multiple Ophthalmic Products Sold at Walgreens
- Altaire Pharmaceuticals, Inc. Issues Voluntary Recall of Multiple Ophthalmic Products

Adverse reactions or quality problems experienced with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program.

## Pharmacists Invited to Participate in NAPLEX Pharmacy Practice Survey

The National Association of Boards of Pharmacy® (NABP®) sent email invitations to randomly-selected pharmacists in all areas of practice encouraging them to participate in the NAPLEX Pharmacy Practice Analysis Survey. Analysis of the survey results is used to evaluate the North American Pharmacist Licensure Examination® (NAPLEX®) competency statements.

The analysis of practice supports the relevance of the NAPLEX competency statements, which define the content for the examination. This analysis helps ensure that competency statements, otherwise known as the examination "blueprint," are in line with pharmacy practice standards and measure the knowledge, skills, and abilities of entry-level pharmacists. In addition, the review supports the NABP mission to protect the public health by providing the state boards of pharmacy with a reliable means of assessing competency that assists them with licensure decisions to support safe and effective practice.

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that based on this rule, it is the pharmacist's responsibility to know the law and rules that govern the practice of pharmacy. Ignorance of the law is never an excuse for failure to comply.

In addition, sections (2)(a) and (2)(f) stipulate respectively:

"(a) A pharmacist and a pharmacy should hold the health and safety of patients to be of first consideration and should render to each patient the full measure of professional ability as an essential health practitioner."

"(f) A pharmacist and a pharmacy should not agree to practice under terms or conditions that interfere with or impair the proper exercise of professional judgment and skill, that cause a deterioration of the quality of professional services, or that require consent to unethical conduct."

As the pharmacy environment becomes increasingly demanding, it is imperative that pharmacists do not lose sight of their ethical and legal responsibilities. Statutes and rules are in place to aid pharmacists in practicing pharmacy in a safe and ethical manner. Failure to follow the rules as required may lead to patient harm and professional disaster.

If you feel you are practicing in an unsafe environment, it is your responsibility to speak up and take action. The Board cannot inject itself into the operations of a business unless those operations are illegal, unethical, or fraudulent.

It is a privilege to practice pharmacy and to have the opportunity to make an impact in our patients' lives. But this privilege requires great responsibility. No one is accountable for your license but you. Pharmacists must remember that they are held to a higher standard than non-licensed individuals involved in the pharmacy business. As the health care professional, the pharmacist must ensure that he or she is practicing in a safe environment, that there is compliance with all applicable statutes and rules, and that patients are the priority.

## *Regulatory Update*

The Board has several rules in the amendment process. These rules may be viewed on the Board's website under the Statutes/Rules tab. Once in the Statutes/Rules tab, choose Proposed Amended Rules Submitted and then select the year. Any rules that have been submitted for revision will be listed.

In particular, the Board is in the process of amending the following rules:

**680-X-2-.14 The Role of Technicians in Alabama**

This proposed change would more clearly articulate the Board's view on technician oversight relative to all entities holding an Alabama permit.

**680-X-2-.44 Collaborative Practice**

This proposed rule would outline the requirements for pharmacists and physicians to engage in collaborative practice.

**680-X-2-.12 Supervising Pharmacist**

Sections (8) and (9) became effective on August 9, 2019.

(8) If the permit holder's supervising pharmacist will be or is no longer employed or no longer desires to act as a supervising pharmacist, the permit holder shall notify the Board within ten (10) days by the submission of an action plan for the designation of another supervising pharmacist. This plan shall not exceed ninety (90) days before the permit holder is in violation of operating a pharmacy without a supervising pharmacist at which time the Board may require closure of the pharmacy until such time as a supervising pharmacist assumes his/her duties.

(9) In the event of a temporary absence by supervising pharmacist of greater than 30 days, the permit holder shall designate a temporary supervising pharmacist with notification to the Board of the name of the temporary supervising pharmacist and the period of time during which he/she shall act as such. The permit holder must notify the Board of the assignment of the temporary supervising pharmacist prior to the time the temporary supervising pharmacist begins to act as such. The permit holder will inform the board of the date of the original supervising pharmacist's return from his/her absence.

## *Reminder*

As a reminder, gabapentin will be rescheduled to Schedule V effective November 18, 2019.

The reclassification of gabapentin will require an inventory of all gabapentin products at the close of business on November 17, 2019, or prior to the open of business on November 18, 2019. This inventory must be documented and retained for two years. All gabapentin products must be included in any future inventories as required by law.

All Alabama-permitted entities with activities involving gabapentin products (or any other state-controlled substance) must obtain and/or maintain an Alabama controlled substance permit.



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