



# Arizona State Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

1616 W Adams St, Suite 120 • Phoenix, AZ 85007 • Website: <https://pharmacy.az.gov>  
Email: [kgandhi@azpharmacy.gov](mailto:kgandhi@azpharmacy.gov)

## Board Members

- Joseph Leyba, PharmD, RPh..... President
- Kristen Snair, CPhT ..... Vice President
- Michael Blaire, RPh..... Member
- Kevin Dang, PharmD, RPh..... Member
- Kyra Locnikar ..... Member (Public)
- Reuben Minkus ..... Member (Public)
- Mohammad (Mo) Salari, RPh..... Member
- Ted Tong, RPh ..... Member
- Lorri Walmsley, RPh..... Member

## The Board Is on Facebook

Follow the Arizona State Board of Pharmacy for the latest news and updates at <https://www.facebook.com/Arizona-State-Board-of-Pharmacy-396869467321193>.

## Update Your Profile

In an effort to communicate more effectively with its licensees and permittees, the Board noticed that contact information in its system is not current and up to date. Please use your online profile to update your contact information.

## Renewal Time Is Here

It is the time of year to check your license and permit to see if you are due to renew. The renewal portal is now open. If you are up for renewal, please visit [https://azbop.igovsolution.com/online/user\\_login.aspx](https://azbop.igovsolution.com/online/user_login.aspx).



This year, the following actions can be taken:

1. License holders:
  - a. Reset username and password
  - b. Update mailing address, contact information, and employer information
  - c. Upload documents (eg, court records, disciplines) – if applicable
2. Permit holders:
  - a. Reset username and password
  - b. Update pharmacist-in-charge, designated representatives, and officer list
  - c. Enter federal employer identification number

- d. Enter United States Drug Enforcement Administration (DEA) registration
- e. Update mailing address and contact information
- f. Upload documents (eg, DEA Form 106, court records, disciplines, surety bond, current Good Manufacturing Practice audit) – if applicable

## Congratulations to the Board's 50-year Pharmacist Licensees

- ◆ Philip Leavitt
- ◆ Patrick O'Brien
- ◆ Dionicia Raines
- ◆ Thomas Reed
- ◆ Susan Sammis



## Deregulation of Nonprescription Retailers

During Arizona's 2019 legislative session, Senate Bill 1170 was passed to deregulate nonprescription retailers. As of August 27, 2019, a nonprescription retailer permit is no longer required to sell over-the-counter (OTC) drugs and devices to customers. If you have a nonprescription retail permit, you do not need to renew it.

## Licensure by Universal Recognition

On August 27, 2019, the Board began accepting applications for licensure by universal recognition.

The universal recognition policy allows Arizona residents to use an out-of-state professional or occupational license to qualify for an Arizona license to work. To qualify, an applicant must:

- ◆ prove residency in Arizona;
- ◆ be currently licensed or certified for at least **one year** in another US state in the discipline applied for and at the same level of practice as recognized in Arizona;
- ◆ be in good standing in all states where currently or previously licensed or certified;
- ◆ have met all applicable education, work, exam, and/or clinical supervision requirements in the other state where originally licensed or certified;
- ◆ complete a criminal background check when required by law;
- ◆ take and pass any applicable exam on Arizona state law; and
- ◆ pay all applicable fees to the Board.

# National Pharmacy Compliance News

October 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.

## **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 psychotherapeutics 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](http://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.

## Technicians' Opioid CE Requirement

By Kristen Snair, CPhT

Technicians, pay close attention to your continuing education (CE) course titles to be sure that you have met the updated requirements. In June 2019, the Board reviewed the existing opioid law, commonly known as the Arizona Opioid Epidemic Act. When reviewing the section that requires professionals who dispense controlled substances to complete a minimum of three hours of opioid-related, substance use disorder-related, or addiction-related CE, the determination was made that this does apply to pharmacy technicians. The Board will accept CE or continuing medical education for the 2019 renewal cycle. The Board website has been updated to reflect this requirement.

## PTCB Update

By Kristen Snair, CPhT

The Pharmacy Technician Certification Board (PTCB) is making the application process easier for certified pharmacy technicians (CPhTs). PTCB has teamed up with the National Association of Boards of Pharmacy® (NABP®) to create a one-stop process. If your CE hours are recorded in CPE Monitor® and meet the requirements, the new process eliminates the need to manually enter CE information and provides “instant” recertification. The steps to participate are as follows:

- ◆ Step 1 – Set up an NABP e-Profile on NABP’s website.
- ◆ Step 2 – Add your PTCB certification number to the credentials section of your e-Profile.

What is CPE Monitor? Here is a quick background in case you were wondering. CPE Monitor is a national, collaborative effort by the Accreditation Council for Pharmacy Education and NABP to provide an electronic system for pharmacists and pharmacy technicians to track their completed continuing pharmacy education (CPE) credits.

Questions about NABP e-Profile? Please visit <https://nabp.pharmacy/help/what-information-do-i-need-to-verify-an-existing-e-profile-or-create-a-new-one>.

## Veterinary Medicine

By Michael Blaire, RPh

According to the 2017-2018 National Pet Owners Survey conducted by the American Pet Products Association, 68% of US households, or approximately 85 million families, own a pet. Companion animals have become an important member of the American family and, not surprisingly, people are willing to spend money on products and services to maintain the health and well-being of their pets. As such, demand is increasing for pharmacists to be informed about disease states and drug therapies suitable for a number of different animal species.

Veterinary medicine has become increasingly more sophisticated and pet owners have become more actively involved in their pets’ care. Likewise, the number of complaints filed against pharmacists by veterinarians and pet owners has increased. It is imperative that pharmacists be well informed about the suitability of dosages, dosage forms, excipients, and look-alike/sound-alike veterinary and human brand name

products when filling a veterinary prescription. It is even more critical when recommending an OTC product.

One excellent resource for pharmacists looking to increase their knowledge of veterinary medications is the *Veterinary Drug Handbook* by Donald Plumb. Available in print or by online subscription, “Plumb’s” is the first place veterinarians and veterinary pharmacists look for answers. Another handy reference is Blackwell’s *Five-Minute Veterinary Consult*, also available in print or online. The *Five-Minute Veterinary Consult* covers essential information on clinical signs, diagnosis, treatment, and follow-up for 838 specific disorders of dogs and cats.\*

Pets are an expanding patient population that present a wonderful opportunity for pharmacists to provide care for the entire family. However, with differences in drug metabolism, anatomy, and sensitivities, these patients present significant challenges as well. Ultimately, it is the pharmacist’s responsibility to ensure that a veterinary prescription is filled accurately and appropriately.

\* The author of this article has no interest, financial or otherwise, in either of these publications.

## Complaint Process and Guidance

By Joanna Deng, PharmD Candidate, Class of 2020, University of Arizona

“I’m going to report this to your supervisor!” How many times have you heard this while working in the pharmacy? What if someone decided to file a complaint against you to the state board of pharmacy? What happens to your license? What can you do about it?



In Arizona, anyone may file a written complaint to the state board of pharmacy against a pharmacist, technician, and even the pharmacy itself. Complaints can also involve arrests, criminal charges, convictions, or disciplinary charges from other states on the licensee. Remember, according to Arizona

Revised Statutes (A.R.S.) §32-3208, you have 10 days to report any misdemeanors or felony charges.

Each complaint received is thoroughly reviewed for validity and evaluated to determine who is involved with the allegations. The Board does not have any authority on pricing/billing discrepancies, insurance claims, and customer service matters; however, if the complaint is found to be within the jurisdiction of the agency, a compliance officer or investigator will be delegated to research the complaint further to determine if the allegations violate any rules or statutes detailed in the *Arizona State Board of Pharmacy Law Book*.

Do not panic when a compliance officer arrives at the pharmacy door to deliver news that there is a complaint against the pharmacy, and do not start sweating when the news is that the complaint is against you. Slow your heartbeat and discreetly wipe off any sweat. The compliance officer is simply there to discuss the complaint with you and to gather pertinent information and materials related to the allegation. Be prepared to provide documentation such as daily signature logs, counseling

*Continued on page 5*

Continued from page 4

logs, compounding logs, computer screen prints, copies of prescriptions, etc. A copy of the complaint will be given to you, and all licensees involved will be given the opportunity to provide a written response sent to the compliance officer. **Always** provide a response to the complaint. The response should address the circumstances leading to the event and any corrective actions that have since been placed.

Once the investigative report and supporting documentation are ready for presentation to the Complaint and Concern Review Committee and the Board, all parties involved with the complaint will be notified of the time and date of the public meeting. The Board will consider the complaint and judge if any violations were made by the licensee or permit holder and may choose to either dismiss the complaint; issue a non-disciplinary advisory letter, a non-disciplinary order for CE, or a consent agreement; or move the case to a conference or formal hearing. At the complaint review, the Board cannot impose discipline; as such, A.R.S. §32-3108 does not apply and the Board is not required to, but may, afford the opportunity to speak if the party is present. If the Board votes to move the case to a conference or formal hearing for further discussion, the presence of the licensee or permit holder will be requested and the time, date, and location of the public meeting will be provided. **Come** to the Board meeting dressed professionally. A conference or formal hearing is when the respondent(s) has the chance to address the complaint and answer any questions from the Board. **Always** tell the truth and state the facts. After discussion, the Board may choose to impose any of the actions previously stated or decide to impose disciplinary action, such as disciplinary CE, civil penalty fines, probation, or ask for voluntary surrender of a license. As health care providers, we strive to provide the best care for our patients and sometimes mistakes can be made and miscommunications can occur; however, actions can also be fraudulent and dishonest. It is the Board's mission to protect the public welfare of Arizona from any unprofessional conduct generated by pharmacies and pharmacy personnel. If you have any questions or concerns, please feel free to contact the Board.



### **USP Is Around the Corner**

The Board encourages permittees to use the following areas in USP Chapter <800> as guidance and a best practice at this time. More information will be provided in future communications.

1. Designation of and document training for the **responsible person**.
2. List of all hazardous drugs (HDs), which must include any item on the current *NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings*.
  - ◆ Perform a **risk assessment** on List 2-3 drugs and drugs that do not appear on *NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings*.
  - ◆ If necessary, develop alternative containment strategies.

3. Personnel training and hazard communication program are in place.
  - ◆ Safety data sheets are available for all HDs.
  - ◆ Develop standard operating procedures (SOPs) for all job functions.
  - ◆ Documentation is maintained for all personnel training.
4. Personal protective equipment (PPE):
  - ◆ Develop SOPs for PPE based on activity being performed.
  - ◆ Specified PPE must be in stock and available.
  - ◆ Where appropriate, PPE should be "fit tested" and documented as part of a more inclusive medical surveillance program.
5. To the extent possible, designate areas for receipt, storage, and compounding of HDs.
  - ◆ Spill kit and eye wash station should be available.
  - ◆ Highest level of powder containment possible with action plan detailing construction and types of containment primary engineering control and containment secondary engineering control ordered to bring facility into complete compliance.
6. Develop and implement SOPs for cleaning, disinfecting, and decontamination of surfaces and equipment.
  - ◆ Complete routine surface wipe testing to validate processes.
7. Implement SOPs for labeling, packaging, transport, and disposal of HDs.
  - ◆ Identify reverse distributor and/or environmental waste disposal.
8. Implement a medical surveillance program.
9. An action plan to finalize the requirements of USP Chapter <800>.

### **Disciplinary Actions and Updates – Health Boards**

Disciplinary actions for the Arizona State Board of Pharmacy, Arizona Medical Board, Arizona Naturopathic Physicians Medical Board, Arizona Board of Osteopathic Examiners, and Arizona Regulatory Board of Physician Assistants can be found at <https://drive.google.com/file/d/0ByEE-sGueI9GcnlhNVFzb2ozVVFSQkdzYkpFbXF4eWlMQ3hJ/view>.

Page 5 – October 2019

The *Arizona State Board of Pharmacy News* is published by the Arizona State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation® (NABPF®) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

Kamlesh "Kam" Gandhi, PharmD - State News Editor  
 Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor  
 Amy Sanchez - Communications Manager