

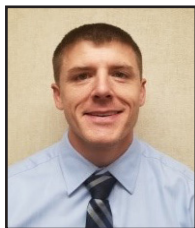


Wyoming State Board of Pharmacy

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<https://pharmacyboard.wyo.gov>

Board Welcomes New Inspector/ Compliance Officer Keith Bennett, PharmD, RPh



The Wyoming State Board of Pharmacy welcomes the newest member of its team, Keith Bennett, PharmD, RPh. Keith began with the Board on September 9 and will serve as one of the Board's inspectors/compliance officers. He graduated with his PharmD from the University of Wyoming and has a background in retail and mail-order pharmacy settings.

Keith is a veteran of the United States Air Force and is a member of the Wyoming Air National Guard. He has served with the military for over 15 years in Security Forces. Prior to coming to the Board, Keith worked at the Civilian Health and Medical Program of The Department of Veterans Affairs (CHAMPVA) Meds by Mail and Walgreens. Keith's experience with both the military and pharmacy settings have been an enormous asset to the Board.

While not a Wyoming native, Keith has lived in Wyoming for over 15 years, beginning when he was stationed here as a member of the US Air Force. Keith and his family have made Wyoming their home and enjoy the outdoors. He is looking forward to having opportunities to engage with pharmacists and technicians around the state.

Renewal Notice

Pharmacist and pharmacy technician licenses are due for renewal. In order to avoid a late fee, licenses must be renewed by December 31, 2019. Licenses may be renewed online at <https://pharmacyboard.wyo.gov>. **You must have completed your continuing education (CE) hours before renewing.** Pharmacists must complete 12 hours of CE, including one and one-half hours on the responsible prescribing of controlled substances and one hour related to immunizations if they are a pharmacist immunizer. Technicians must complete six hours of CE.

Thank You to Jan Shatto, CPhT

Board members and staff want to thank Jan Shatto for her time as an appointed member from April 2014 to August 2019. The Board is appreciative of the time and commitment that she provided. Thank you Jan, for a job well done and best wishes.

Update on USP Compounding Standards

On June 1, 2019, US Pharmacopeial Convention (USP) published revisions to USP General Chapters <795> Pharmaceutical Compounding—Nonsterile Preparations and <797> Pharmaceutical Compounding—Sterile Preparations. After publication of the revised and new compounding standards, USP received appeals on certain provisions in Chapters <795> and <797>.

In accordance with USP's bylaws, the responsible expert committees worked with a sense of urgency to consider the information raised in the appeals and issued decisions on the appeals. In accordance with USP's formal appeals process, stakeholders who submitted appeals on the compounding chapters have requested further review by an appointed panel.

USP's bylaws provide that the official date of a standard under appeal must be postponed while an appeal is pending. In light of these appeals, USP is postponing the official dates of the revised Chapters <795> and <797>.

USP General Chapter <800> is not subject to any pending appeals and became official on December 1, 2019. During the postponement and pending resolution of the appeals of Chapters <795> and <797>, Chapter <800> is informational and not compendially applicable. USP encourages utilization of Chapter <800> in the interest of advancing public health.

However, USP Chapter <797> has already been incorporated by reference into the Wyoming Pharmacy Act Rules Chapter 17. The Board has instructed the inspectors/compliance officers to educate sterile compounders on the

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National Pharmacy Compliance News

December 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.

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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revisions and to continue to inspect for compliance to the May 2017 version of USP Chapter <797>. Both versions are available from the Board office at 1712 Carey Avenue, Suite 200, Cheyenne, WY, 82002.

Notice of Intent to Amend Rules

The Board proposes to amend Chapters 10 and 16 of the Wyoming Pharmacy Act Rules and Regulations. The amendments in Chapter 10 clarified sections, cleaned up redundancies, corrected formatting and grammar issues, as well as deleted the prohibition on technician in training permit renewals and deleted the pharmacist-to-technician ratio. The amendments in Chapter 16 included:

- ◆ the deletion of redundant definitions,
- ◆ inclusion of a definition for “high risk minors,”
- ◆ reorganization of sections,
- ◆ designation of Basic Life Support as the approved certification,
- ◆ an update to incorporate by reference the current Centers for Disease Control and Prevention guidelines for immunizations,
- ◆ removal of the requirement for epinephrine to be of the auto-inject variety,
- ◆ deletion of the requirement to provide the patient with two copies of the Immunization Questionnaire and Consent Form,
- ◆ an update to the length of time to keep these on file for two years, and
- ◆ deletion of the requirements for sponsoring organizations to keep the records for six years.

The Board also proposes to create a new Chapter 9 of the Wyoming Controlled Substances Act Rules and Regulations. This chapter is being created to provide the exemptions to the seven-day prescribing limit required in Wyoming Statute 35-7-1030(e), which states:

(e) No practitioner shall prescribe nor shall any person dispense any opioid or combination of opioids for acute pain to an opioid naive patient for

more than a seven (7) day supply in a seven (7) day period. The board shall by rule establish reasonable exceptions to this section, in consultation with other professional licensing boards that license practitioners, including exceptions for chronic pain, cancer treatment, palliative care and other clinically appropriate exceptions. As used in this subsection:

(i) “Opioid” means an opiumlike compound that binds to one (1) or more of the major opioid receptors in the body;

(ii) “Opioid naive patient” means a patient who has not had an active opioid prescription in the preceding forty-five (45) day period.

Requests for copies of the proposed amendments may be addressed to the executive director at the Wyoming State Board of Pharmacy at 1712 Carey Avenue, Suite 200, Cheyenne, WY, 82002, or to BOP@wyo.gov. The proposed amended rules and new chapters are posted on the Wyoming Secretary of State website at <http://rules.wyo.gov>. Comments may be submitted to the Board at the address above or to BOP@wyo.gov on or before 5 PM MDT March 20, 2020.

Recent Disciplinary Action

H.Y., Pharmacist License #2076: Failed to complete 12 hours of CE in 2018. Administrative penalty of \$500 plus required to complete 12 extra hours of CE, including three hours on pharmacy law.

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