



Kansas State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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Announcements

New Features in eLicense!

- ◆ Update contact and employment information at any time (not just during renewal)
- ◆ Reset password without having to re-register
- ◆ Select a status (active, probation, etc) to filter license or registration verifications

Proposed Regulatory Changes

The Kansas State Board of Pharmacy is currently considering changes to the pharmacy technician ratio requirements for permanent pharmacy closures and clarification of the pharmacist-in-charge (PIC) notification of resignation to the Board. The Board regularly reviews, updates, and adopts new or amended regulations to be consistent with current pharmacy practice and to align with its mission of protecting the public health. During that process, the Board is required to provide notice to the public, a minimum 60-day public comment period, and a public hearing on each regulation for consideration. Information about these changes can be found on the Board website under "Proposed Regulatory Changes." Visit <http://pharmacy.ks.gov/statutes-regs/proposed-changes> for more information.

Follow Us on Social

Follow the Board on Twitter @KSBOP or on Facebook (www.facebook.com/KansasStateBoardOfPharmacy) for news, updates, and more!

Welcome Staff

The Board extends a warm welcome to new Administrative Assistant Lesa Pritz. Ms Pritz is originally from Topeka, KS. She was a customer service representative for Breathe Oxygen Medical Supply and worked at various banks in Topeka prior to joining the Board staff in September 2019. Ms Pritz and her husband (who also works for the state of Kansas) have two grown children and three dogs. The Board is very excited to have her in this role, providing exceptional customer service to licensees, registrants, and members of the public, and assisting with Board meetings.

What Does Compliance Look Like?

- ◆ **Incident Reports:** The pharmacist shall prepare a report containing the name of each pharmacy employee and the license or registration number of each employee involved. The prepared report shall have the signatures of all pharmacy employees involved in the incident. Please note this includes

all pharmacists, interns, and registered technicians. Kansas Administrative Regulations 68-7-12b(c)(2) and (c)(6).

- ◆ **Current CPR Certificate:** To administer vaccines under the authority of Kansas Statutes Annotated (K.S.A) 65-1635a, pharmacists or pharmacy interns must have taken a CPR course and have a current CPR certificate available upon inspection. The CPR certificates are to be maintained for a period of five years as a part of the vaccination record. The Board will accept online CPR courses for recertification only.
- ◆ **First and Last Name of Prescriber's Agent:** All prescriptions received, whether controlled or non-controlled, must have the first and last name of the prescriber's agent on the prescription. K.S.A 65-1637(b), (c), and (d).
- ◆ **Theft/Loss Reporting:** Pharmacies can report to the Board the same way the pharmacies report to Drug Enforcement Administration (DEA). No separate form is required for Board reporting purposes. If the amount of the theft/loss is below the DEA reporting threshold, but is in any way related to a potential or suspected theft or diversion, notification to the Board is still required. The Board needs to know about any diversion event, even if it was minimal, quickly identified, and/or stopped.

New Distributor, Third-Party Logistics Provider, and Outsourcing Facility Requirements

Pursuant to Article 14 of the Board's regulations, Kansas now requires registration of wholesale distributors, third-party logistics providers, and outsourcing facilities located in Kansas or shipping into Kansas. In addition, the Board has established requirements for registration, personnel, operation, records, maintenance, etc. Because of the changes, facilities will be required to fill out new applications. In addition, facilities will be required to provide proof of satisfactory inspections within certain time periods. While these changes go into effect mid-December 2019, the Board has granted a waiver through June 30, 2020, to afford facilities sufficient time to comply and minimize any economic impact.

In January, information will be sent to each pharmacy or distributor registered with the Board with detailed instructions related to these changes. Please review this information and be prepared! The Board recognizes that some facilities have been registered in Kansas in other categories and will require shifting to a new registration category. Those facilities will complete

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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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that process during the 2020 renewal period (May 4 – June 30, 2020) to avoid duplication of fees. Facilities planning to apply for additional registrations will have six months to complete this process (ending June 30, 2020).

2020 Retail Dealer Renewals

The Board retail dealer permits expire **February 29, 2020**. Permits may be renewed either online or by mail from mid-January through February 29, 2020. For renewal instructions, visit www.pharmacy.ks.gov.

- ◆ **Online:** Use the Board's secure online payment portal to renew each permit. If you do not have a username and password or have forgotten, under Existing Licensee Registration, click "Sign-Up" and create a username and password. Large corporate entities can batch-renew all relevant permits at the same time. Log in to the account and select "Renew License," where you can complete your renewal, pay the renewal fee by credit/debit card or electronic check, and **immediately print the 2020 permit(s)**. Electronic renewals must be date/time-stamped on or before 11:59 PM CST on February 29, 2020.
- ◆ **Mail:** Paper forms can be found on the Board website and can be filled out electronically for individual or multiple permits. The forms must be postmarked or hand-delivered no later than February 29, 2020, to the Board office along with a check or money order made payable to the **Kansas State Board of Pharmacy**. Please allow 10 business days for staff to process your renewal. To verify that your renewal has been processed, visit the License Verification page on the website and check for the updated expiration date.

Failing to renew on or before 11:59 PM CST on February 29, 2020, will result in your permit being canceled. You will then be required to complete a new application. The facility cannot sell non-prescription medications until the new application is submitted and approved by the Board.

WELL. AWARE. Balanced Self-care.

Recently, the Board partnered with the Kansas Pharmacists Association (KPhA) and Kansas Pharmacists Recovery Network (KsPRN) to compile resources for pharmacists, technicians, students, and interns related to wellness. The Board has noted an increase in criminal, Board discipline, and impaired provider cases that often evolved from anxiety, depression, stress, burnout, or other mental health issues. As a group of health care professionals, it is imperative that the pharmacy community seeks and receives support for ongoing health and wellness needs within the profession. Please take some time to review the new wellness program: "WELL. AWARE. Balanced Self-care." The free KPhA website includes screening tools, statistics on risk and professional awareness, treatment resources, education, and more. For more information, visit <https://kansaspharmacistsassociation.wildapricot.org/Health-Wellness>. The Board is also working with the School of Pharmacy to include pharmacy students in the initiative. Special thanks to KPhA, KsPRN, and the University of Kansas School of Pharmacy for their work in addressing this important issue.

Revoked Technicians

In an effort to provide greater transparency to pharmacists, the Board will publish a list of revocations against Kansas pharmacy technicians in its quarterly *Newsletter*. The Board encourages the PIC to verify the registration status of all employed technicians at least twice a year (June and November is recommended).

The Board's license verification website is a secure and primary source of credential verification information, as authentic as a direct inquiry to the Board: <https://ksbop.licensesoftware.com/portal.aspx>.

Please take notice of the Board's revocation action taken on these registrations:

- ◆ Adams, Gloria, 14-01364, Case 19-142
- ◆ Adee, Taylor, 14-102649, Case 19-144
- ◆ Baurain, Thomas, 14-16232, Case 19-149
- ◆ Canaday, Doris, 14-18952, Case 19-160
- ◆ Carter, Tanya, 14-101622, Case 19-161
- ◆ Doan, Tram, 14-01740, Case 19-170
- ◆ Franklin, Tyesha, 14-101546, Case 19-038
- ◆ Gray, Chad, 14-101568, Case 19-180
- ◆ Harrison, Felicia, 14-18086, Case 19-182
- ◆ Hinojosa, Mildred, 14-18848, Case 19-186
- ◆ Jackson, Alexis, 14-16970, Case 19-193
- ◆ Kimmins, Lashanequa, 14-105216, Case 19-069
- ◆ Kou, Alena, 14-102735, Case 18-661
- ◆ Kuck, Sarah, 14-102755, Case 19-202
- ◆ Mars, Kayleigh, 14-101450, Case 19-212
- ◆ Martin, Laurice, 14-04642, Case 19-213
- ◆ McClure, Marcia, 14-07508, Case 19-378
- ◆ Morales, Maritza, 14-107307, Case 19-102
- ◆ Parsons, Tayler, 14-107743, Case 19-324
- ◆ Quaranta, Pasquale, 14-14728, Case 19-234
- ◆ Rhynerson, Tera, 14-103980, Case 18-508
- ◆ Sarmiento, Dannie, 14-17528, Case 19-243
- ◆ Schauf, Jolene, 14-105238, Case 19-133
- ◆ Shields, Rebecca, 14-17254, Case 19-246
- ◆ Smith, Bettie, 14-16448, Case 19-247
- ◆ Tabor, Debra, 14-07104, Case 19-255
- ◆ Terry, Amenta, 14-102382, Case 19-258
- ◆ Vaughn, Suzanne, 14-100113, Case 19-131
- ◆ Wilkerson, Kathryn, 14-102158, Case 19-263
- ◆ Williams, Telicia, 14-103006, Case 19-265
- ◆ Wilson, Andrienna, 14-16284, Case 19-266

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