October 2019

News

Oklahoma State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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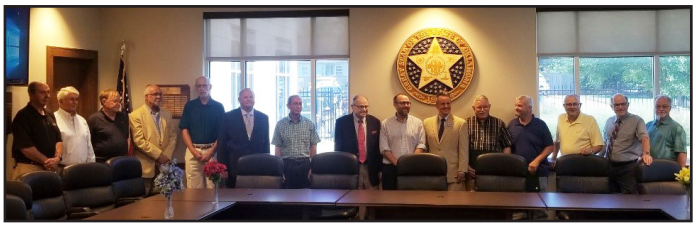
19.14 New Public Board Member Appointed by Governor Stitt

Jason Willeford was appointed to the Oklahoma State Board of Pharmacy by Governor Kevin Stitt in July 2019. His term will run coterminous with the governor and will expire on January 9, 2023. Mr Willeford replaces Stephen Dudley, who served as the Board public member since 2011.

19.15 Oklahoma Pharmacist Receives Governor's Commendation for 60 Years of Active Licensure

Executive Director Marty Hendrick, PharmD, DPh, presented John "Pat" Farrell, DPh, of Enid, OK, with a Governor's Commendation on August 20, 2019. Mr Farrell was licensed as an Oklahoma pharmacist in 1959 and is the oldest actively practicing pharmacist in the state of Oklahoma! Director Hendrick was quoted in the *Enid News* regarding this commendation, saying, "To have this kind of career, with all the changes in pharmacy we've had since he started, is a real testament to the man's work ethic. We have so many people younger than him who decide the technology has moved past them, and they'll retire, but Mr. Farrell has stuck with it, and he is as sharp as can be." Congratulations, Mr Farrell!

19.16 Oklahoma Pharmacists Recognized for 50 Years of Licensure



There are 57 Oklahoma pharmacists still renewing their licenses who were licensed in 1969. Four of those individuals were presented with a "50-Year Certificate" at the Oklahoma Pharmacists Association Annual Meeting, 12 were presented their certificates at the Board's 50-year reception, and the remaining 41 who could not attend either event received their certificates by mail. Pictured above are the 12 pharmacists who attended the

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National Pharmacy Compliance News

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NABPF
National Association of Boards of Pharmacy Foundation

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.

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reception, along with John "Pat" Farrell (recipient of a 60-year Governor's Commendation), Board member Justin Wilson, DPh, and Executive Director Marty Hendrick.

19.17 From the Inspector's Desk

Important Reminders About Transferring Schedule II CDS

- A pharmacy can only transfer a Schedule II controlled dangerous substance (CDS) to appropriately licensed entities (eg, pharmacies, doctors' offices).
- The supplying pharmacy **must** have a "drug supplier" permit reflected on its license.
- A Drug Enforcement Administration (DEA) Form 222 **must** be completed and an invoice must be provided.
- The pharmacy must follow Oklahoma Administrative Code 535:15-7-2. Drug supplier requirements:

  (c) Records. Separate records of sales will be kept on file by the pharmacy. The files will include, but not be limited to, invoices of sales with name and address of purchaser, quantity sold, drug description, price, and date of transaction. These files must be readily available for inspection.

Failure to comply with all of the above will, at a minimum, result in a warning notice issued to the pharmacy, pharmacist-in-charge, or both.

19.18 Pharmacy Licensure Requirements in Oklahoma

Any nonresident pharmacy that ships or delivers drugs into the state of Oklahoma must hold a current Oklahoma pharmacy license. If an Oklahoma pharmacy is shipping or delivering drugs outside the state of Oklahoma, please be sure to check with each specific state's board of pharmacy to verify compliance with its rules and regulations – each state is different! This law applies to services such as MatchRX.

19.19 Verifying Correct DEA Numbers When Filling Prescriptions

DEA has issued the following warning: with each CDS prescription filled, the pharmacist must verify the DEA number for the prescribing physician based on the physician's practice site from where the prescription was issued. Although they are federal licenses, DEA numbers are state-specific; physicians may hold numerous DEA numbers based on where they practice. This is especially common among prescribing physicians who practice close to state lines. DEA numbers can be verified through DEA's website anytime.

19.20 Technician to Pharmacist Ratio

When the technician to pharmacist ratio exceeds 2:1, all technicians in excess of that ratio must wear a proper ID tag that corresponds to the job duty being performed, which should also correlate to the work schedule for all support personnel.

19.21 Out-of-State Mid-Level Provider Prescribing

Reminder: as of November 1, 2018, Oklahoma-licensed pharmacies can fill **non-CDS** prescriptions from out-of-state advanced practice registered nurses (APRNs), physician assistants (PAs), and optometrists.

In order to fill a CDS prescription from an out-of-state APRN or PA, both the mid-level provider and the supervising physician must be licensed in Oklahoma. The APRN and PA need to have valid Oklahoma Bureau of Narcotics (OBN) and DEA licenses for the state of Oklahoma. The name of the supervising physician must be listed on the hard copy CDS prescription. The name of the mid-level provider must be listed on the prescription label.

In order to fill a CDS prescription from an out-of-state optometrist, the optometrist must be licensed in Oklahoma and have valid OBN and DEA licenses for the state of Oklahoma.

19.22 Disciplinary Actions

April 17, 2019

Mindy Winters, Technician #22082 – Case No. 1555: Guilty on three counts, including theft of merchandise. **Revoked.**

Tiffany Pryor, Technician #23657 – Case No. 1556: Guilty on four counts, including theft of CDS. **Revoked.**

Your Rx Pharmacy, Inc #99-6439 – Case No. 1557: Respondent's request to reinstate canceled license is denied. The Board will not consider reinstatement until respondent appears before the Board to respond to questions. Respondent is found guilty on three counts, including shipping into Oklahoma without first procuring a current license from the Board. **$12,000 fine.**

June 12, 2019

Carla Howard, Technician #13143 – Case No. 1558: Guilty on four counts, including failing to follow pharmacy procedure by taking two refill authorizations for herself. **Revoked.**

Dat Tan Nguyen, DPh #17310 – Case No. 1559: Respondent failed to appear to answer to the violations of the complaint. Respondent will refrain from practicing as a pharmacist during the suspension of his pharmacist license. Respondent may petition the Board to appear and request that the suspension be lifted. Respondent is found guilty on four counts, including failure of a pharmacist or pharmacy manager to fulfill responsibilities; every pharmacy shall be licensed if Oklahoma is the state from which or into which it delivers, distributes,

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or dispenses dangerous drugs, medicines, chemicals, or poisons for the treatment or prevention of diseases. **Indefinite suspension.**

Kyle Swinford, Technician #22483 – Case No. 1560: Guilty on six counts, including theft of CDS. **Revoked.**

Kylie Nelson, Technician #16858 – Case No. 1561: Guilty on six counts, including theft of merchandise and CDS. **Revoked.**

August 14-15, 2019

Stephanie Blackmon, Technician #23075 – Case No. 1562: Guilty on five counts, including theft of CDS. **Revoked.**

James Carter, DPh #7921 – Case No. 1565: Respondent shall attend a law seminar in addition to the required 15 hours of continuing education (CE) during the calendar years of 2020 and 2021, for a total of 23 hours of CE during each of those calendar years. All hours of required CE that respondent is to attend during the calendar years of 2020 and 2021 shall be live. Respondent is prohibited from any compounding activities utilizing bulk powder. Respondent admits guilt on all 25 counts, including failing to conduct business in conformity with all federal, state, and municipal laws at all times. **$25,000 fine.**

Steele Drug Company #12-4458 – Case No. 1566: Respondent admits guilt to all 24 counts, including failing to conduct business in conformity with all federal, state, and municipal laws at all times and failing as a pharmacy that engages in compounding to assign every compound preparation an appropriate beyond-use date. **$24,000 fine.**

Terrell Moorhead, DPh #8615 – Case No. 1567: Respondent shall attend a law seminar in addition to the required 15 hours of CE during the calendar years of 2019 and 2020, for a total of 23 hours of CE during each of those calendar years. All hours of required CE that respondent is to attend during the calendar years of 2020 and 2021 shall be live. Respondent is to successfully complete the community pharmacies' risk assessment for medication safety written by the Institute for Safe Medication Practices by September 16, 2019. Respondent admits guilt on all six counts, including failure to establish and maintain effective controls to prevent prescription errors or misfills. **$6,000 fine.**

Calendar Notes

- **Upcoming Holidays:** The Board office will be closed on November 11, 2019, for Veterans Day; November 28-29, 2019, for Thanksgiving; and December 24-25, 2019, for Christmas.
- **Upcoming Board Meetings:** The Board is scheduled to meet on October 16, 2019, and November 20, 2019. All meetings begin at 8:30 AM.

Change of Address or Employment?

Please be diligent in keeping your information up to date and if possible, remind your coworkers and employees. Failure to notify the Board is a violation of Oklahoma pharmacy law. All pharmacists, technicians, and interns must notify the Board in writing within 10 days of a change of address or employment. Online updates through the license renewal page are also accepted as official notification.

Special Notice About the Newsletter

The *Oklahoma State Board of Pharmacy Newsletter* is an official method of notification to pharmacies, pharmacists, pharmacy interns, and pharmacy technicians registered by the Board. Please read them carefully. The Board encourages you to keep them for future reference.

Oklahoma Pharmacists Helping Pharmacists

If you or a pharmacist you care about is suffering from chemical dependency, there is a solution. Oklahoma Pharmacists Helping Pharmacists (OPHP) is readily available for help. Pharmacists in Oklahoma, Texas, and Louisiana may call the OPHP help-line at 1-800/260-7574 ext 5773. All calls are confidential.

This publication is issued by the Oklahoma State Board of Pharmacy as authorized by Title 59 O.S. 353.7. Copies have not been printed but are available through the agency website. [74 O.S. §3105 and 65 O.S. §3-114]

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