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News

Washington State Pharmacy Quality Assurance Commission

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No. 1327 New Executive Director Appointment

The Washington State Pharmacy Quality Assurance Commission is very pleased to announce the appointment of Lauren Lyles-Stolz, PharmD, to the executive director position vacated by Steve Saxe's retirement. The selection process was led by a panel of Commission members and Washington State Department of Health (DOH) representatives. Dr Lyles-Stolz was confirmed by the Commission on September 13, 2019, and started on November 1.

Most recently, Dr Lyles-Stolz served as a German Chancellor Fellow with Siemens Healthineers in Berlin, Germany. She researched population health management mainly in Germany and the United States as a solution to rising health care costs and the fragmented health care infrastructure leading to sub-optimal outcomes. The fellowship included leaders in various disciplines from China, Russia, Brazil, India, and the US to develop solutions for today's and tomorrow's societal challenges. She has also had the uncommon opportunity to meet with population health and health care experts in Singapore, Israel, Scotland, Spain, and Switzerland.

Dr Lyles-Stolz graduated with her doctor of pharmacy degree from the University of Mississippi School of Pharmacy. Following graduation, she completed her postdoctoral fellowship at Eli Lilly and Co in US and international regulatory policy and strategy. The fellowship entailed combining her patient experiences throughout her pharmacy curriculum, background from national pharmacy associations (National Association of Chain Drug Stores, National Community Pharmacists Association), and Food and Drug Administration with the pharmaceutical industry to improve market access for innovative therapies for patients. She also worked part-time as a pharmacist at a mail-order pharmacy, making sure that the right medications got to patients in the criminal justice system. Following that, Dr Lyles-Stolz served as the manager of pharmacy affairs at the Academy of Managed Care Pharmacy, which primarily represents the professional interests of pharmacists and physicians in managed care to help facilitate the transition to value-based health care.

The Commission is looking forward to Dr Lyles-Stolz joining the team!

No. 1328 USP Delays Official Dates for Revised Compounding Chapters

On September 23, 2019, the US Pharmacopeial Convention (USP) announced that the revisions to USP Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations; USP Chapter <797> Pharmaceutical Compounding – Sterile Preparations; and new USP Chapter <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging will no longer be official or effective on December 1, 2019, as previously anticipated. USP also announced that USP Chapter <800> Hazardous Drugs—Handling in Healthcare Settings would become an official chapter but would be considered informational only and not compendially required. There is currently no anticipated date for when these chapters will become official or compendially required.

The Commission is aware of the uncertainty that this delay has on its licensees and other entities engaged in constructing compliant compounding facilities. At the October 25, 2019 business meeting, the Commission decided to continue to allow early adoption of USP Chapter <800>. Due to USP Chapter <800> being considered informational by USP, it will not be effective or enforced until official effective dates are set by USP. Pharmacist inspectors will continue to provide technical assistance on questions of compliance and facility implementation.

In addition to the delays in effectiveness of the revised USP chapters, the Commission withdrew its position to allow for early adoption of the revised chapters and new USP Chapter <825>. This means that the 2008 official USP Chapter <797> and the 2014 official USP Chapter <795> will remain the enforceable standards in Washington for compounding of medications under Revised Code of Washington (RCW) §18.64.270(2).

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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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Licensees should remember that USP chapters are applicable when they are engaged in the preparation of compounding products. To determine if you are engaged in compounding, please refer to the definition of compounding in RCW §18.64.011, which is "the act of combining two or more ingredients in the preparation of a prescription." This means that reconstitution, adding flavor to a medication, etc, are considered compounding in Washington and require compliance with USP. The Commission has adopted several guidance documents on how licensees can comply with USP sterile and nonsterile compounding chapters. These can be found on the Commission's "Policies, Procedures and Guidelines" web page or by following the links below.

- Guidance Document #61: USP General Chapter <795> – Nonsterile Compounding – Information
- Policy Statement #60: Regulation of the Handling of Hazardous Drugs (USP Chapters <797> and <800> and Washington State Department of Labor and Industries Rules)

No. 1329 Ancillary Utilization Plans and Pharmacist to Technician Ratios

Do your pharmacy's ancillary utilization plans (AUPs) include staffing ratio information? With recent rule changes that eliminated a standard ratio, the Commission is asking all responsible pharmacy managers (RPMs) to review their AUPs to ensure that the numbers reflect current practice if ratios or staffing numbers are included in their plans. Any pharmacy that has a specified ratio in its AUPs must follow that ratio or the pharmacy must revise the plans and resubmit them for Commission approval. Note, AUPs are not required to include staffing ratio information.

AUPs reviewed during an inspection that are not consistent with the pharmacy's current practice due only to staffing numbers will not receive a deficiency; however, the inspector will inform the RPM of the process for filing revised plans.

No. 1330 Notification of Theft or Significant Loss of Controlled Substances

Washington Administrative Code 246-887-020 requires that in the event of a significant loss or theft, a Drug Enforcement Administration (DEA) Form 106 must be completed and copies must be sent to DEA and to the Commission office.

Title 21 Code of Federal Regulations §1301.76 requires registrants to notify the local DEA field division office in writing of a theft or significant loss of any controlled substances within one business day of **discovery.** The registrant must **also** complete and submit, to the local DEA field division office, a DEA Form 106 regarding the loss or theft.

A copy of the initial notification is **not** required by the Commission. Please send a copy of the DEA Form 106 by email to wspqac@doh.wa.gov or by fax to 360/236-2260.

No. 1331 Updates – Nonresident Pharmacies and HB 1412

During the 2019 Washington Legislative Session, the legislature passed House Bill (HB) 1412, an act relating to nonresident pharmacies. HB 1412 amends RCW §18.64.360 to require a nonresident pharmacy to submit a copy of an inspection report that has substantially equivalent standards to those of the Commission and was issued within the last two years of application for initial licensure or renewal of a license.

This change in law aligns the Commission's standards for nonresident pharmacies with those of resident pharmacies, continuing its efforts to ensure patient safety.

The Commission sent letters to all licensed nonresident pharmacies informing them of this change in law. Those currently licensed in Washington State do not need to submit an approved inspection report until they renew in 2020. Any new pharmacy will need to submit an approved inspection with its application.

The Commission established a list of states with inspection standards that are substantially equivalent to those in Washington State. That list has been posted on the Commission's web page. If a pharmacy is in a state that is not on the approved list but has a nonresident inspection report done by a state that is on the approved list, the Commission will accept that.

The National Association of Boards of Pharmacy® Verified Pharmacy Program® has also been identified as an approved third-party inspection.

The standards used to determine equivalency were based on the state requirement of meeting the minimum standards of USP. For those pharmacies that do not compound, the Commission has created a chart identifying from which additional states the Commission will accept inspection reports. In order for those additional inspection reports to be accepted, the pharmacy will have to attest on its application that it does not compound. If a pharmacy begins compounding, it will need to submit an approved inspection report.

This law became effective on July 28, 2019.

No. 1332 Rules Rewrite

The Commission continues its work on updating its rules to meet current practice. The language has been sent out regularly and comments continue to be received. At the Commission meeting on September 12, 2019, it was decided that the rules should be incorporated into a single chapter rather than the current four individual buckets.

The single chapter will begin with a General Provisions section, which includes all definitions, prescription and labeling standards, and the identification of legend drugs and the Uniform Controlled Substances Act. The second part will be

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General Licensing, which covers all the requirements for each credential, license, and registration that the Commission has jurisdiction over. The third part will be Professional Standards, which identifies the standards by which all credentialed personnel will have to abide. Finally, the fourth section will be Operational Standards, identifying all the standards with which facilities licensed by the Commission as well as other registrants and wholesalers must abide.

These updated rules will be sent out to the public. The Commission held a three-day meeting on October 23-25, 2019, with the goal of finalizing the language. The Commission anticipates a public hearing date in March 2020 with the rules becoming effective on July 1, 2020.

Comments on the rules may be sent to PharmacyRules@doh.wa.gov.

No. 1333 Suicide Prevention – Pharmacist Survey

Since 2017, pharmacists in Washington State have been required to participate in training on suicide prevention. In the 2019 legislative session, the focus on suicide prevention through education and research was extended.

As part of the Commission's efforts, a survey will be sent to pharmacists to continue to gain information on suicide prevention and application of the training in the workplace. Health care professionals are in a unique position to notice depression and suicide warning signs in their patients and to intervene early. Your feedback is valuable.

A few facts about suicide:

- Most people who attempt and die by suicide have a mental health condition, although it is often not diagnosed.
- Many people who consider and attempt suicide have never seen a behavioral health specialist.
- A study found that almost 40% of people have a health care visit within a week before their suicide attempt.

Along with the survey, which will follow later this year, the legislature has also directed the Commission to distribute suicide prevention materials for pharmacies to make available and provide to patients as they deem appropriate.

- Suicide Prevention Materials (1).pdf
- Suicide Prevention Materials (2).pdf
- Suicide Prevention Materials (3).pdf

No. 1334 Recognition of 50 Years of Active Licensure in Washington State

The Commission wishes to acknowledge and congratulate the following pharmacists for 50 years of active licensure in Washington State. Thank you for your dedication to your profession and to the practice of pharmacy. The Washington State Pharmacy Association will award certificates of service to the following pharmacists at its annual meeting in November 2019.

Janet Abbott	Gordon Tambellini	Loyal Brock
Sharon Sutton	Carol Vanhorn	Larry Morgan
Vicky McFarlane	Paul Hendrickson	William Jolly
William Fassett	Wade Schutze	
Mary Kuehn	Senator Linda Evans Parlette	

No. 1335 GovDelivery – Stay Informed and Get Involved

Why join GovDelivery? GovDelivery is the communication platform that allows you to self-select content that interests you. It lets you determine when and how you receive information. Do not miss out! Get updates from the Commission to stay compliant with the latest changes in rules and laws, as well as opportunities for you to share your voice in all things related to pharmacy. Have the *Newsletter* delivered straight to your personal or business email inbox. You can change or cancel your subscription at any time.

The Commission currently has four topic lists that can be found in the drop-down list of Health Systems Quality Assurance after you sign in:

- Pharmacy Commission Meeting and Agenda
- Pharmacy Commission Newsletter
- Pharmacy Commission Rules
- Rx Fraud Alert

General interest topics under the Department of Health include:

- Disciplinary News Releases
- DOH News Releases
- Opioid Updates
- Implementation of HB 1427
- Secure Medication Returns

The *Washington State Pharmacy Quality Assurance Commission News* is published by the Washington State Pharmacy Quality Assurance Commission 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.

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