April 2019

News

Washington State Pharmacy Quality Assurance Commission

Published to promote compliance of pharmacy and drug law

Dept. of Health • PO Box 47852 • Olympia, WA 98504-7852
www.doh.wa.gov/LicensesPermitsandCertificates/ProfessionsNewReneworUpdate/PharmacyCommission.aspx

No. 1312 Executive Director Recruitment

The Washington State Department of Health (DOH) and the Washington State Pharmacy Quality Assurance Commission will begin the recruitment process for a new executive director to replace Steven Saxe, RPh, FACHE, when he retires on October 1, 2019. This will be an exciting opportunity for a pharmacist leader interested in carrying on the next phase of the Commission's work, such as rewriting the pharmacy rules. DOH expects to post the recruitment in early spring at *www.doh.wa.gov.*

No. 1313 Commissioner Elizabeth Jensen Retires

Elizabeth Jensen, PharmD, BCACP, was appointed to the Commission by then-Governor Christine Gregoire in 2011 and represented clinical practice and rural pharmacy practice. Reappointed to the Commission in 2015 by Governor Jay Inslee, Elizabeth ended her tenure at the January 2019 business meeting. As a commissioner, Elizabeth served as vice chair; participated on subcommittees related to technology, business practices, and donation prescription drugs; served as Commission observer in the accreditation process for the University of Washington; and took part in many other Commission activities. Elizabeth served with a passion for public health and pharmacy practice. The Commission wishes Elizabeth and her family a prosperous future.

No. 1314 Measles Outbreak

Governor Inslee declared a state of emergency in all counties in response to confirmed cases of measles in Washington. Measles is extremely contagious and can be serious, especially for young children. More information is available on the DOH website.

This measles outbreak also creates some uncommon situations given the presence of active disease, treatment, or return-to-work advice or letters. Pharmacists and their authorizing prescribers who receive questions about treatment (such as for post-exposure prophylaxis) or requests for return-to-work letters, should refer these individuals to their local public health department or to the Clark County Public Health measles call center, which can be reached by calling 360/397-8021.

All return-to-work/school authorizations during an outbreak or for notifiable conditions must come from the health officer or be provided under the health officer's direct orders. For a list of notifiable conditions, visit *https://www.doh.wa.gov/forpublichealthandhealthcareproviders/notifiableconditions/listofnotifiableconditions.* Clark County Public Health will also help exposed individuals determine whether they are eligible for post-exposure prophylaxis.

No. 1315 Rules Rewrite Update

The Commission embarked on a rule rewrite to create concise rules that provide guardrails for patient safety while allowing for flexibility to support innovation and changes in technology. The Commission created four buckets to provide a guide to licensees, so that they know where they need to look. The first bucket, professional standards, was reviewed at the January Commission meeting, and Operational Standards and General Provisions were reviewed at the March Commission meeting. Changes from these meetings will be incorporated into a draft that will be sent out to stakeholders so the Commission can continue the process of receiving public feedback.

The next big part of the project will be creating a crosswalk between the Commission's current rules and the new ones. This will allow for stakeholders and licensees to identify the new home for the rules that apply to them and to easily find what has been kept the same, amended, or removed.

The Commission plans to have these new rules effective by July 1, 2020.

No. 1316 Public Rules Hearing – Pharmacist-to-Technician Ratio

The Commission will hold a public rules hearing to consider rules to eliminate a standard pharmacist-to-pharmacy technician ratio. The rules hearing, scheduled for April 26, 2019, at 1:15 PM, provides an opportunity for the Commission to review comments and accept testimony on proposed amendments to Washington Administrative Code (WAC) 246-901-130. The

continued on page 4

National Pharmacy Compliance News

April 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.

FDA Launches Pilot Program to Improve Security of Drug Supply Chain With an Innovative Approach

Food and Drug Administration (FDA) has launched a pilot program allowing participants representing the various parts of the drug supply chain to pilot innovative and emerging approaches for enhanced tracing and verification of prescription drugs in the United States' supply chain. The program is in line with FDA's ongoing efforts to prevent suspect and illegitimate products from entering the supply chain, according to an FDA press release. Eligible manufacturers, repackagers, and other stakeholders can apply to participate in the program, which will inform the development of the enhanced electronic, interoperable track-and-trace system for industry set to go into effect in 2023 in accordance with the Drug Supply Chain Security Act (DSCSA), enacted by Congress on November 27, 2013.

The pilot technologies of this program may become part of FDA's enhanced expectations for reliable track-and-trace systems, which will be designed to reduce diversion of drugs distributed domestically and to keep counterfeit drugs from entering the supply chain. The DSCSA pilot project program is intended to help identify and evaluate the most efficient processes to comply with and apply drug supply chain security requirements and will aid in identifying attributes the system will need for enhanced product tracing and verification, as well as electronic means to share the information. FDA recently issued draft guidance on the use of product identifiers with a unique serial number to improve verification down to the package level. FDA has also provided draft guidance for verification systems to quarantine and investigate suspect and illegitimate drugs.

Additional information on the FDA pilot program is available in a February 8, 2019 announcement in the *Federal Register.*

FDA Announces New Efforts to Increase Oversight and Strengthen Regulation of Dietary Supplements

Noting that three in four Americans now take at least one dietary supplement on a regular basis, and that the dietary supplement industry has expanded to include as many as 80,000 different products for consumers, FDA Commissioner Scott Gottlieb, MD, has announced new plans to increase the agency's oversight of dietary supplements. These initiatives include communicating to the public as soon as possible when there is a concern about a dietary supplement on the market, ensuring that the regulatory framework is flexible enough to adequately evaluate product safety, and continuing to work closely with industry partners. FDA is also developing new enforcement strategies to respond to entities that violate standards established under the Dietary Supplement Health and Education Act of 1994.

On February 11, 2019, FDA sent 12 warning letters and five online advisory letters to foreign and domestic companies that are illegally selling more than 58 products. The products are illegally marketed as unapproved new drugs that make unproven claims about preventing, treating, or curing Alzheimer's disease, as well as a number of other serious diseases and health conditions, such as diabetes and cancer. In his statement, Gottlieb noted that most stakeholders in the industry act responsibly, but he expressed concern over the ability of bad actors to exploit the system by providing potentially dangerous products and making unproven or misleading claims about the health benefits supplements may offer.

FDA is planning a public meeting on this topic during the second quarter of 2019. For more information, view the FDA statement at *https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm631065.htm.*

Trump Administration Releases National Drug Control Strategy to Reduce Drug Trafficking and Abuse

As the opioid crisis continues to claim the lives of tens of thousands of Americans each year, the Office of National Drug Control Policy has released its *National Drug Control Strategy.* The *Strategy* breaks down the administration's priorities in addressing the crisis, with an emphasis on three areas: prevention, treatment and recovery, and reducing availability.

- **Prevention** efforts are focused on educating both consumers and caregivers about the dangers of opioid misuse and include a new national media campaign, continued efforts to expand prescription monitoring programs (PMPs), and improving the ability of state, local, and tribal communities to identify and prevent substance abuse.
- **Treatment and recovery recommendations** in the *Strategy* include improving access to naloxone, improving evidence-based addiction treatment, and eliminating barriers for accessing treatment.

- **Reducing availability** strategies are focused on disrupting illegal supply chains, defeating drug traffickers, increased cooperation with international partners, and combating illegal internet drug sales.

The document notes that the "most important criterion of success" is saving lives and calls for the federal government to work closely with state and local governments, as well as other stakeholders. Additional information, including the full strategy document, is available on the White House website at *https://www.whitehouse.gov/opioids.*

National Association of Boards of Pharmacy® (NABP®) and its member boards of pharmacy remain committed to advancing best practices for PMPs in the interest of public health. NABP's PMP data sharing system, NABP PMP InterConnect®, facilitates the secure transfer of PMP data across state lines and provides an effective means of combating drug diversion and drug abuse nationwide. In addition, NABP and its member boards continue efforts to educate consumers about prescription drug safety. The NABP $AWAR_XE$® Prescription Drug Safety Program's Drug Disposal Locator Tool has more than 6,000 disposal locations and continues to add new locations to provide consumers with a safe way to dispose of medication and help prevent misuse and abuse of prescription medications. For more information about PMP InterConnect and the $AWAR_XE$ program, visit the Initiatives section of the NABP website at *www.nabp.pharmacy.*

New Study Predicts Opioid Epidemic Will Worsen Over the Next Decade

More than 700,000 people will die from opioid overdoses between 2016 and 2025, and annual overdose deaths will reach nearly 82,000 by 2025, estimates a new study published to *JAMA Network Open.* The estimate is based on an analysis of data from the National Survey on Drug Use and Health and the Centers for Disease Control and Prevention from 2002 to 2015.

Researchers also projected that intervention efforts focused on lowering the incidence of prescription opioid misuse would help to reduce the number of deaths 3.8% to 5.3%, a figure the researchers described as "modest," due to the changing nature of the opioid crisis. The study notes that more people are directly initiating opioid use with illicit opioids rather than prescription drugs, and illicit opioids have become more lethal with the availability of illegally manufactured fentanyl.

The researchers encourage policymakers to take "a stronger and multipronged approach" to reduce the impact of the ongoing opioid overdose epidemic. The full article is available at *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2723405.*

FDA Warns of Potential Blood Pressure Medication Shortages Due to Recalls

FDA is warning health care providers and consumers of a shortage of angiotensin II receptor blockers, commonly used to treat high blood pressure. A growing list of medications containing valsartan, losartan, and irbesartan have been recalled from the market for containing an impurity that may present a cancer risk to patients. The issue was first detected in the summer of 2018, according to a statement posted to the FDA website. Since then, FDA has placed a Chinese manufacturer of the active ingredient on import alert to stop their imports, and FDA is working with other manufacturers to recall affected medications.

In the statement, FDA notes that the risk to individual patients remains very small, but that there is still reason to be concerned about the potential health risks. Medications with these impurities are believed to have been in the market for about four years.

"Now that these risks are identified, we're applying what we've learned to the evaluation of similar manufacturing processes where we now know these risks could arise," the statement notes. The FDA press release is available at *https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm629796.htm.*

FDA Releases Two Draft Guidances Related to REMS Programs

FDA has released two new draft guidances to ensure risk mitigation programs put in place for certain drugs and biologics, as required for approval, are working. The agency's primary risk management tool is FDA-approved product labeling. However, in limited cases, FDA may require a Risk Evaluation and Mitigation Strategy (REMS) to help ensure a drug's benefits outweigh its risks.

The following guidances relate to the assessment of REMS programs:

- **REMS Assessment: Planning and Reporting Guidance for Industry** describes how to develop a REMS Assessment Plan.
- **Survey Methodologies to Assess REMS Goals That Relate to Knowledge Guidance for Industry** provides recommendations on conducting REMS assessment surveys to evaluate patient or health care provider knowledge of REMS-related information.

FDA states that the goal in providing this guidance for REMS is to ensure constant improvement of their safety programs and establish the most efficient and effective programs moving forward, to optimize patient care and keep consumers safe and healthy. More information on REMS is available on the FDA website at *https://www.fda.gov/drugs/drugsafety/rems.*

continued from page 1

hearing will be held at the DOH headquarters in Tumwater, WA. You can view the proposed language, significant legislative analysis, and post a comment on DOH's Rules Comment web page. The official public comment period ends on April 19, 2019.

No. 1317 Chapter 246-887 WAC – Updated

The rules implementing the Uniform Controlled Substances Act have a new look. The Commission adopted amendments to Chapter 246-887 WAC under Washington State Register (WSR) 19-06-068, which were filed on March 5, 2019, and are effective as of April 5, 2019. The reformatting of the chapter removed substances already established in Chapter 69.50 Revised Code of Washington (RCW), thereby eliminating redundancy and providing an efficient means for updating the RCW in the future. The amendments update citations to federal rules and laws adopted by the Commission. The amendments also incorporate changes proposed by rulemaking petitions from the Washington State Office of the Attorney General – Consumer Protection Division and Greenwich Biosciences by adding substances to Schedule I and Epidiolex® to Schedule V.

No. 1318 Defining Emergency Medical Reasons

The Commission filed an interpretive statement to advise and clarify to pharmacists and to the public its current definition of emergency medical reasons as it is used in WAC 246-879-010(10)(e). The Commission does not interpret the meaning in the same way as Food and Drug Administration, in that the borrowing, lending, selling, purchasing, or transferring of medications between pharmacies to a practitioner to alleviate a temporary shortage or for another emergency medical reason does not constitute wholesaling. The Emergency Medical Reasons – Interpretive Statement was filed with the Washington State Legislature Office of the Code Reviser under WSR 19-07-062 on March 19, 2019. It is on the Commission's "Policies, Procedures and Guidelines" web page.

No. 1319 Legislative Update

The 2019 legislative session is under way. The Commission is following two pieces of requested legislation, along with a couple of other key bills that will affect the profession.

House Bill (HB) 1412 is one of the two pieces of agency request legislation the Commission put forward this year. This bill would require nonresident pharmacies to provide the Commission with an inspection report of sustainably equivalent standards upon the renewal of their license. This would create parity between in-state pharmacies and out-of-state pharmacies, ensuring that they are held to the same standards, while at the same time protecting patient safety. This bill is awaiting a vote on the House floor.

HB 1331 and Senate Bill 5380 comprise the governor's bill to address the opioid epidemic. Incorporated into this bill is the Commission's second piece of agency request legislation that would remove the requirement for the Commission to approve electronic prescribing systems. This bill also does a number of things aimed at reducing the number of deaths from opioids. Included in this is also the expansion of standing orders for opioid reversal medication, clarification regarding the allowance for partial fills of opioids, and clarification regarding the allowance for hospitals to distribute naloxone from emergency departments. Both of these bills are moving through the legislative process and will likely be updated as they move, based on stakeholder input.

The Commission staff holds a weekly legislative call on Fridays at 12:10 PM. You can join by webinar, using the webinar ID 685-746-787, or you can listen to the discussion by calling in to 877/309-2074, using the access code 854-241-261. During the call, the Commission reviews the status of bills and discusses any changes that have happened.

No. 1320 Apply to Serve the People of Washington as a Commission Member

The Commission is accepting applications to fill two pharmacist-member positions and one public-member position on the Commission. This recruitment is to fill positions that will become vacant in January 2020.

The Commission is looking for public-spirited people willing to study the issues and make decisions in the public's best interest. The Commission seeks diversity in its members and recognizes the value that variety brings in understanding and serving the people of Washington State.

Public member applicants may not have any affiliation with any aspect of pharmacy, and pharmacist applicants must be licensed pharmacists in Washington for five years before their appointment and while serving on the Commission. All members must be citizens of the United States and residents of Washington.

The governor is the appointing authority for Commission members. To apply, visit Governor Inslee's Boards & Commissions web page. For more information on qualifications or for answers to questions regarding roles and responsibilities, please visit the Commission's web page or contact the Commission office at 360/236-4834 or wspqac@doh.wa.gov. Recruitment closes on June 1, 2019.

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.

Steven Saxe, RPh, FACHE - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Amy Suhajda - Communications Manager