May 2020 News



Oregon State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

800 NE Oregon St, Suite 150 • Portland, OR 97232

No. 627 Board Member News

The Oregon State Board of Pharmacy welcomes two new members, Nichole Watson and Mishele Dufour, and fondly appreciates the dedicated service of outgoing member, Dianne Armstrong.

Nichole Watson is the Board's new public member. She is a classroom teacher who is currently working with the Portland Association of Teachers as developer of racial equity and community partnerships. An Oregon native, Nichole graduated with a bachelor's degree in social science and a master's degree in education from Portland State University. In pursuit of lifelong learning, she decided to strengthen her practice by pursuing a doctorate in educational leadership at Lewis & Clark College. As a classroom teacher and servant in her community, she wholeheartedly believes her highest priority is protecting the health, safety, and wellbeing of the students and families she serves. Likewise, advocacy, promoting wellness, and providing the best available information to citizens and licensees of Oregon are central to her deepest beliefs. Nichole understands that these goals align with the purpose of the Board.

Mishele Dufour is the Board's new pharmacy technician member. Mishele has worked as a certified pharmacy technician in Oregon for 17 years. She has experience in retail and hospital pharmacies and taught pharmacy technicians in an American Society of Health-System Pharmacists-accredited technician program at Chemeketa Community College. In addition to her current role of pharmacy analyst at Salem Health, Mishele also serves on the Pharmacy Services Committee for 340B Health and the Optimum Learning Environment Charter Board for her daughter's school. Mishele was the Oregon Society of Health-System Pharmacists pharmacy technician of the year in 2017. Her diverse experiences will provide insight and understanding to a wide scope of pharmacy practice and make her a great fit for this role.

Dianne Armstrong served as one of the Board's first two pharmacy technician members, appointed in 2016. She brought knowledge and expertise as well as thoughtful contemplation in preparation for Board meetings. The Board's accomplishments and activities during Dianne's tenure included celebration of the Board's 125th anniversary; hosting the 2016 National Association of Boards of Pharmacy® (NABP®)/American Association of Colleges of Pharmacy District Meeting; the Board's receipt of the NABP Fred T. Mahaffey Award in 2017 for pharmacist prescribing of contraceptive therapy; the implementation of landmark legislative directives, including pharmacist prescriptive authority for contraceptives, naloxone, and insulin refills; as well as efforts related to the Public Health and Pharmacy Formulary Advisory Committee initiatives. Dianne's contributions and participation helped in the development of biennial licensure for pharmacists and established new types of registrations and rules to keep up with evolving practices in the industry, which most recently included the adoption of Division 045 compounding rules.

Dianne's straightforward, compassionate, and thoughtful spirit will truly be missed. The Board and staff thank Dianne very much for her time dedicated as a special steward of public protection!

No. 628 COVID-19 Update From Board's Executive Director

We have all heard the phrase "we are all in this together," which has never been more true than during an infectious disease pandemic. Everyone is at risk for contracting the coronavirus disease 2019 (COVID-19) infection, and the more successful you are at maintaining infection prevention measures (eg, social distancing, hand hygiene), the less likely you are to become infected. Essential public health and safety workers are called upon to interact with many people throughout the workday. We applaud the bravery and commitment of frontline pharmacists, interns, and pharmacy

continued on page 4

OR Vol. 41, No. 1 Page 1

National Pharmacy Compliance News



May 2020

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.

President Trump Signs Legislation Extending Schedule I Status for Fentanyl Analogues

A law to extend the Schedule I status of fentanyl analogues for another 15 months was signed into law by President Donald J. Trump on February 6, 2020. Synthetic fentanyl analogues, often illegally manufactured, are widely believed to be fueling the "third wave" of the opioid crisis, as detailed in the October 2019 issue of *Innovations* (pages 8-11), which can be accessed through the Publications section of the National Association of Boards of Pharmacy "s website.

In February 2018, Drug Enforcement Administration (DEA) issued a temporary order to establish fentanyl-related substances as Schedule I. The Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act extends the DEA order, which was set to expire on February 6, 2020. The bill requires the Government Accountability Office to produce a report within 12 months on the public health and safety effects of controlling fentanyl-related substances, according to *Homeland Preparedness News*.

Drug Overdose Deaths Related to Prescription Opioids Declined by 13% in 2018

Fatalities related to the use of prescription opioids declined by 13% in the United States during 2018, according to the 2019 National Drug Threat Assessment released by DEA. Despite this encouraging news, the report makes it clear that the opioid crisis continues at epidemic levels. Specifically, controlled prescription drugs remain a major factor in the record number of overdose deaths since 2017. Benzodiazepines and antidepressants were involved in an increasing number of overdose deaths.

Fentanyl and similar synthetic opioids also remain a major point of concern. Fentanyl maintained high availability through most of the US in 2018. Illegally manufactured versions of the powerful opioid continue to be smuggled into the US, primarily in the form of counterfeit pills made to look like prescription opioids and powder. Fentanyl remains the "primary driver" of the current opioid crisis, according to the report.

"Illicit drugs, and the criminal organizations that traffic them, continue to represent significant threats to public health, law enforcement, and national security in the United States," a DEA press release states. "As the National Drug Threat Assessment describes, the opioid threat continues at epidemic levels, affecting large portions of the United States."

Drug-Resistant Infections Are Increasing

A new report on antibiotic infections released by the Centers for Disease Control and Prevention (CDC) estimates more than 2.8 million antibiotic-resistant infections occur each year, and more than 35,000 Americans are dying annually as a result. While the report notes that prevention and infection control efforts in the US are working to reduce the number of infections and deaths caused by antibiotic-resistant germs, the number of people facing antibiotic resistance is still too high. "More action is needed to fully protect people," the report states.

The report lists 18 antibiotic-resistant bacteria and fungi and places them into three categories (urgent, serious, and concerning) based on clinical impact, economic impact, incidence, 10-year projection of incidence, transmissibility, availability of effective antibiotics, and barriers to prevention. It also highlights estimated infections and deaths since the last CDC report in 2013, aggressive actions taken, and gaps that are slowing progress.

The full report is available on the CDC website.

NASEM Report Recommends Framework for Opioid Prescribing Guidelines for Acute Pain

Contracted by Food and Drug Administration (FDA), a December 2019 report by the National Academies of Sciences, Engineering, and Medicine (NASEM) seeks to develop evidence-based clinical practice guidelines for prescribing opioids for acute pain. The report, Framing Opioid Prescribing Guidelines for Acute Pain:

Developing the Evidence, also develops a framework to evaluate existing guidelines, and recommends indications for which new evidence-based guidelines should be recommended.

As part of its work, NASEM examined existing opioid analgesic prescribing guidelines, identified where there were gaps in evidence, and outlined the type of research that will be needed to fill these gaps. NASEM also held a series of meetings and public workshops to engage a broad range of stakeholders who contributed expert knowledge on existing guidelines, and provided emerging evidence or identified specific policy issues related to the development and availability of opioid analgesic prescribing guidelines based on their specialties.

"We recognize the critical role that health care providers play in addressing the opioid crisis – both in reducing the rate of new addiction by decreasing unnecessary or inappropriate exposure to opioid analgesics, while still providing appropriate pain treatment to patients who have medical needs for these medicines," said Janet Woodcock, MD, director of FDA's Center for Drug Evaluation and Research in a statement. "However, there are still too many prescriptions written for opioid analgesics for durations of use longer than are appropriate for the medical need being addressed. The FDA's efforts to address the opioid crisis must focus on encouraging 'right size' prescribing of opioid pain medication as well as reducing the number of people unnecessarily exposed to opioids, while ensuring appropriate access to address the medical needs of patients experiencing pain severe enough to warrant treatment with opioids."

FDA will next consider the recommendations included in the report as part of the agency's efforts to implement the SUPPORT Act provision requiring the development of evidence-based opioid analgesic prescribing guidelines.

The report can be downloaded for free on the NASEM website.

New Research Shows Pharmacists Positively Impact Hospital Care Transitions

Patients who received focused attention from pharmacists during hospital stays expressed higher satisfaction, according to research presented at the American Society of Health-System Pharmacists Midyear Clinical Meeting and Exhibition. The study centered on the effect of pharmacists educating patients about medications as they transitioned out of hospital care. During the study, pharmacists reconciled patients' medications before discharge, talked with patients about the medications they were taking, and contacted them by phone after discharge to discuss their care.

Of the 1,728 patients included in the study, 414 received the full transition-of-care education protocol, including a follow-up pharmacist phone call. Those patients showed a 14.7% increase in the overall average mean score, as measured by the Hospital Consumer Assessment of Healthcare Providers and Systems survey, which assesses patients' perceptions of their care after discharge. A post hoc analysis also showed that 30-day readmission rates dropped from 17.3% to 12.4% when a post-discharge phone call was made to patients as a part of the study.

"Pharmacists play a multitude of vital roles for patients during a hospital stay, including comprehensive medication management and ensuring medication safety. Now, they can feel increasingly confident about their role in helping patients when transitioning from different levels of care. Our findings add to growing literature demonstrating that pharmacist involvement in hospital discharge improves outcomes and safety," said Katherine L. March, PharmD, BCPS, clinical pharmacy specialist at Methodist University Hospital in Memphis, TN, in a press release.

continued from page 1

technicians who have put themselves at risk to provide essential pharmaceutical care services to the public during this time of anxiety and uncertainty. The Board is working tirelessly to support the front lines and will assist in any way that promotes the protection of public health, safety, and welfare. The Board continues to answer licensee and registrant questions, issue licenses and registrations, sustain pharmacy student progress, and issue temporary rules and guidance to navigate through this extraordinary time. We are all in this together and will get through it together!

No. 629 Board Inspections: Interns' Perspective

By PJ Toor and Holly Mousa, PharmD Candidates 2020, Pacific University School of Pharmacy and Adam Gattis, PharmD Candidate 2020, Oregon State University, College of Pharmacy

As interns at the Board, our advanced pharmacy practice experiences were likely our first time being exposed to the Board and the inspection process. It was an eye-opening experience to see the inspection purpose and processes, and to understand that the Board's entire focus is on the legalities related to patient safety. The opportunity provided us with some helpful points about pharmacy inspections that we will share.

Organization is key. Having a good grasp of where all pertinent documents and passwords are to efficiently provide requested information is helpful to both you and the inspector. Be sure you know how to quickly pull up temperature logs and quarterly reports. The inspector will ask for these items. As you work on accessing those, the inspector will be walking around the pharmacy, continuing to inspect your refrigerators, shelves, records, etc, which in turn increases the odds that he or she will find something you may have missed during your self-inspection. It is possible that the inspector will arrive during a time when the pharmacist-in-charge (PIC) is not working. Therefore, all staff members should be reviewing the self-inspection form and be aware of the location of all documents listed on page two of the form in order to be able to assist the inspector when he or she arrives. Being prepared for an inspection will decrease the imposition on your pharmacy's workflow and expedite the review.

When in doubt, refer to the laws and rules concerning the operation of pharmacy! Often, Board staff members are asked questions that can be answered simply by referring to the laws and the rules. If you have a lack of understanding about the rules concerning the operation of a pharmacy, it is your responsibility to learn and become compliant. As a PIC, you are entirely responsible for what happens in the pharmacy, and saying that you were not aware of a rule does not exempt you from the responsibility of doing things correctly.

Documentation is your best friend. If an inventory count is off and you figure out why, make a note, and sign and date it. Every small note helps to clarify a discrepancy for an inspector. It is likely that months down the road you will not remember the details of every small situation when asked. You do not want to discover that your pharmacy has a diversion issue by a Drug Enforcement Administration investigator arriving at your counter.

Lastly, read the Board's *Newsletter*. It is an easy way to stay up to date with changes. Print each issue of the *Newsletter* out each time and leave a copy in the pharmacy for all staff to peruse on their own time. These tips will help the pharmacy inspections run smoothly and decrease the likelihood of errors being caught at inspection time.

No. 630 Online Services Update

The Board's new licensing interface, MyLicense eGov, now supports online applications for new pharmacists, interns, certified Oregon pharmacy technicians, and nonprescription drug outlets (Class A and C). Additionally, all current licensees can now create an account to renew a license; update contact information, address, and employment information; and order certified copies. Facilities can update mailing address information, order certified copies, and, in some cases, renew online. Instructions on how to link to an account and log in to the new system are available on the Board's website. The Board will be working to enable online services for additional facility registration types in the future.

Page 4 – May 2020

The Oregon State Board of Pharmacy News is published by the Oregon State Board of Pharmacy 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.

Joe Schnabel, PharmD, RPh, BCPS - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor &
Executive Editor
Amy Sanchez - Communications Manager