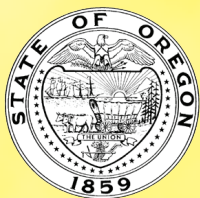


August 2020

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. 631 Board and Staff Member News

The Oregon State Board of Pharmacy wishes to recognize outgoing member, **Roberto Linares**. Roberto's time on the Board was filled with change. He brought a diverse perspective from the Oregon State University College (OSU) of Pharmacy as an educator as well as his active practice in the community pharmacy setting. Roberto's insights have proven to be essential in guiding the Board's critical policy discussions of the past eight years. Above all else, Roberto has been a staunch patient safety advocate.

Some of the Board's accomplishments and activities during Roberto'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, and the Board's receipt of the NABP Fred T. Mahaffey Award in 2017 for pharmacist prescribing of contraceptive therapy. Roberto served as Board president in 2015-2016 and is the only remaining member who served with three different executive directors during his time on the Board. Roberto has taken this role very seriously, always keeping the mission of the Board at the forefront. The Board is ever grateful for his willingness to share his deep understanding of the profession and his appreciation that the work done here has an impact on people, whether they are patients served or Board licensees. Roberto, thank you for eight years of service to the Board. You will be missed!

The Board welcomes **Ian Doyle** as its new pharmacist member. Ian is currently the associate dean for pharmacy practice and associate professor at Pacific University School of Pharmacy, where he started as an assistant professor in 2010. Ian obtained his doctor of pharmacy degree at the University of the Pacific in Stockton, CA, in 1993, and completed a residency in pharmacy practice at Oregon Health Sciences University in 1994. His professional interests include kidney transplantation medication management, leadership and professional development, and pharmacy practice policy advancement. For over 25 years, his roles as pharmacy practitioner, manager, and educator have evolved with ever-increasing responsibilities, including leadership

and supervisory guidance. He has applied his expertise in pharmacy practice toward management of pharmaceutical care, patient and staff education, management of improved performance and outcomes, and team-based implementation of service protocols. Ian has served on several professionally related boards at Pacific University, the Oregon Society of Health-System Pharmacists, and the Oregon State Pharmacy Association. He has also volunteered with his homeowner's association and the Salem Triathlon Club. In his free time, Ian enjoys participating in triathlons and golfing.

The Board is also pleased to introduce the newest pharmacy inspector, **Jennifer Davis**. Jennifer comes to the Board with an extensive background in community pharmacy practice. She is a 2003 PharmD graduate from the University of Georgia College of Pharmacy and completed a PGY1 community-based pharmacy practice residency with the University of Arizona College of Pharmacy. She began working for The Kroger Co/Fred Meyer in high school as a pharmacy clerk/technician and spent the bulk of her professional career in a variety of roles with the company, ranging from float pharmacist to pharmacy manager to clinical coordinator. Most recently, she served as the director of pharmacy for the Student Health Services Pharmacy at OSU College of Pharmacy.

During her employment at both Fred Meyer and OSU, she directed their respective PGY1 community-based residency programs. Jennifer is a familiar face across the profession, having participated in several committees, work groups, and serving as president of the Oregon State Pharmacy Association in 2013-2014. Oregon pharmacists recognized her with the Distinguished Young Pharmacist (2009) and Pharmacist of the Year (2018) awards for individual excellence and outstanding contribution to the pharmacy association and community. In her spare time, she enjoys volunteering to support foster kids and families, and quenching her wanderlust by traveling all over the United States and around the world as often as possible with her family and friends.

Additionally, the Board acknowledges the well-earned retirement of compliance secretary, **Annette Gearhart**. After

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National Pharmacy Compliance News

August 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.

FDA Releases MOU on Human Drug Compounding Regulation and Oversight

Acknowledging the vital role states play in reducing the risks associated with compounded drugs, Food and Drug Administration (FDA) has made available a [Final Standard Memorandum of Understanding \(MOU\) Addressing Certain Distributions of Compounded Human Drug Products](#), intended to be entered into between the agency and the states. The release of the MOU is required as part of its [submission to the Office of Management and Budget](#) for review and clearance under the Paperwork Reduction Act of 1995. The MOU was developed in close [consultation with the National Association of Boards of Pharmacy](#)[®] (NABP[®]), as described in the Federal Food, Drug, and Cosmetic Act. The agency also engaged with states, pharmacies, associations, pharmacists, and other stakeholders.

Among the issues addressed in the MOU is the definition of the statutory term “inordinate amounts,” which refers to compounded drugs that are distributed interstate. In addition, the MOU includes the risk-based oversight model from the 2018 revised draft MOU. States that sign the document agree to identify pharmacy compounders that distribute inordinate amounts (greater than 50%) of compounded drug products interstate, as well as report certain information to FDA about those compounders. FDA also provided clarity in the MOU on state investigations of complaints associated with compounded drugs distributed out of state. States that enter into the MOU will investigate complaints about drugs compounded at a pharmacy within their state and distributed outside of the state and advise FDA when they receive reports of serious adverse drug experiences or serious product quality issues, like drug contamination.

To help states to better investigate these issues, FDA has also announced an agreement with NABP to make an information sharing network available to the states. Through this network, states will be able to obtain information from pharmacies in their states and transmit that information to FDA.

“We anticipate the final MOU, once signed, will help to facilitate increased collaboration between the FDA and the states that sign it,” said Janet Woodcock, MD, Director, Center for Drug Evaluation and Research, in an [FDA Voices](#) article. “Working together, we can

help promote quality compounding practices and better address emerging public health concerns that may affect patients.”

FDA Clarifies Compounding Rules, Offers Flexibility to Help Ease Drug Shortages During COVID-19 Pandemic

FDA noted it will use discretion in enforcing certain standards related to 503A and 503B compounding in an effort to ease drug shortages during the coronavirus disease 2019 (COVID-19) pandemic. During an American Pharmacists Association (APhA) webinar on April 30, 2020, the agency clarified it will “look to 503B compounders to grapple with drug shortages” and “turn to 503A compounders to fill in the gaps.”

In addition, the agency clarified that medications on the FDA drug shortage list are effectively considered “not commercially available,” which frees 503A and 503B compounding facilities from limits on compounding drugs that are “essentially a copy” of a product already available on the market. FDA also does not intend to take action if a 503A facility fills orders for a compounded drug that is essentially a copy of an approved drug that has been discontinued and is no longer marketed.

In April 2020, FDA issued a temporary guidance that granted flexibility for pharmacists to compound certain necessary medications under 503A for nonspecific patients hospitalized due to COVID-19. In addition, a temporary guidance was issued that granted enforcement flexibility for 503B outsourcing compounding facilities for drugs in shortage for patients hospitalized during the COVID-19 public health emergency. The guidance documents stipulate the conditions compounders must meet and are available at <https://www.fda.gov/media/137125/download>.

More information on these compounding rule clarifications is available in a May 5, 2020 press release on the [APhA website](#).

CMS Allows Pharmacies to Temporarily Enroll as Clinical Diagnostic Laboratories for COVID-19 Testing

Centers for Medicare & Medicaid Services (CMS) has released a document detailing a process that allows pharmacies to temporarily enroll as independent clinical diagnostic laboratories. This process will allow those

facilities to seek Medicare reimbursement for COVID-19 tests, making it easier for them to provide that service during the pandemic.

“Up until this point in time, most pharmacies could only offer this as a cash service because they were not considered providers through CMS, and really a lot of the third-party payers really didn’t have an interest in a fee-for-service type model,” said Michael E. Klepser, PharmD, FCCP, pharmacy professor at Ferris State University, in an interview with *Bloomberg Law*. “The fact that CMS is saying we’re now authorizing or allowing pharmacists to get reimbursed for these is a great door opening at the federal level and that’s a huge, huge thing.”

Chain pharmacies such as CVS, Walgreens, and Rite Aid are offering drive-through testing at many pharmacies throughout the country.

FDA Issues Updated Guidance for Compounding Pharmacies Experiencing PPE Shortages

FDA has issued an update for its guidance to pharmacy compounders that may experience shortages of personal protective equipment (PPE) during the COVID-19 pandemic. As compounders typically utilize PPE when performing sterile compounding, the updated guidance clarifies that the drugs can be compounded under the policy in a segregated compounding area that is not in a cleanroom. This policy has been adopted to ensure patients continue to have access to medicines they need during the pandemic, and to reduce the risks of compounding when standard PPE is not available.

In addition to FDA guidance, United States Pharmacopoeial Convention has previously issued an informational document for compounders regarding garb and PPE shortages during the pandemic. The document includes recommendations for conserving garb and PPE and what steps might be considered in the case of shortages of garb and PPE used for both sterile and nonsterile compounding.

The updated guidance can be accessed through FDA’s website by visiting www.fda.gov/media/136841/download.

HHS Expands Telehealth Access in Response to COVID-19

In an effort to prevent and respond to the COVID-19 pandemic, the US Department of Health and Human

Services (HHS) has awarded \$20 million to increase telehealth access and infrastructure for health care providers and families. The funds, which are awarded through the Health Resources and Services Administration (HRSA), will increase capability; capacity and access to telehealth and distant care services for providers, pregnant women, children, adolescents, and families; and assist telehealth providers with cross-state licensure.

“This new funding will help expand telehealth infrastructure that is already being used during the pandemic to provide essential care, especially to the most vulnerable, including pregnant women and children with special health care needs,” said HHS Secretary Alex Azar in a press release. “This funding will also help clinicians use telehealth nationally by streamlining the process to obtain multi-state licensure.”

HRSA’s Maternal and Child Health Bureau awarded a total of \$15 million to four recipients; each award supports a key area in maternal and child health, including pediatric care, maternal health care, state public health systems, and family engagement for children with special health care needs. HRSA’s Federal Office of Rural Health Policy awarded a total of \$5 million to two recipients through the Licensure Portability Grant Program, which will assist telehealth clinicians nationally on licensure and credentialing to meet emerging needs related to COVID-19.

Criminals Found Posing as CDC Representatives to Steal Money and Information

Centers for Disease Control and Prevention (CDC) is warning the general public of a new type of phone and phishing scam by criminals posing as CDC representatives, often requesting donations. According to CDC, most of these fraudulent activities are being conducted by phone, utilizing software to “spoof” phone calls to make them appear as if they are coming from phone numbers that may look familiar. CDC advises consumers to avoid answering calls from numbers they do not recognize, and to avoid sharing personal information over the phone. In addition, CDC notes that no federal agency will request donations from the general public. Suspicious phone calls may be reported to the Federal Communications Commission.

More information on the scams is available on the CDC website at <https://www.cdc.gov/media/phishing.html>.

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over 32 years of state service with the Board, Annette looks forward to enjoying time with family, friends, and her garden paradise!

Though Annette can never be replaced, the Board extends a warm welcome to **Elizabeth Hughes**. Elizabeth grew up in rural West Virginia before moving to the city to attend Marshall University and pursue a bachelor's degree in literary studies. After graduating, she moved to Vancouver, WA, so that she could attend Portland State University and earn her master's degree in book publishing. Upon exiting the academic world, she began working at an animal hospital in Vancouver, interacting with all sorts of exciting pets and animals. In her spare time, Elizabeth enjoys reading and binge-watching sci-fi shows. She and her fiancé, Jordan, plan to get married this fall. They share two mischievous cats and a collection of tropical houseplants.

No. 632 CCCE Information

In 2019, the legislature passed [House Bill 2011](#) and Governor Kate Brown signed it into law on May 30, 2019. It has an operative date of July 1, 2021. Oregon's health boards are directed to write rules, specific to the licensees impacted and the number of hours that are to be required. In February 2020, the Board discussed the various policy items to incorporate into continuing education rules; however, rulemaking efforts were stalled due to the pandemic. It is anticipated they will resume rulemaking efforts in late 2020 or early 2021, to be effective in alignment with the law (July 1, 2021). This means that registered pharmacists (RPhs) and certified pharmacy technicians (CPTs) will be audited for complying with cultural competency continuing education (CCCE) requirements for licensing cycles thereafter. For example, with the RPh licensure/renewal cycle being July 1, 2021, through June 30, 2023, pharmacists will be audited for CCCE completed in that date range. Auditing occurs after the renewal cycle is complete, therefore to be audited after July 1, 2023, then ongoing biennially. For CPTs, the first effective date range will be July 1, 2022, through June 30, 2024 – audited for CCCE after July 1, 2024, then ongoing biennially.

No. 633 Updated Website Is Now Live

After 13 months of hard work and dedication, the Board is pleased to announce that the agency's new website launched on June 5, 2020. The goal was to provide current and relevant information presented in an easy-to-navigate format that is also user friendly. The Board reviewed, revised, and organized years' worth of content while keeping within the boundaries of state mandates for website redesign. This new platform provides a simpler way to browse information, a streamlined search engine, and "buckets" that house relevant information in groups, such as "Applicants" and "Resources." The Board's website is one, if not the most important, method used to communicate with licensees. Based on the positive feedback

received, the Board believes the new site will continue to positively benefit its licensees, stakeholders, and all end users going forward. Thank you for your patience as you learn to navigate the new site!

No. 634 Pharmacy Organizations Unite to Take a Stand Against Racial Injustice

Thirteen national pharmacy associations, including NABP, have signed a [joint statement](#) against racial injustice. The Board fully supports the call to action of this statement and will work diligently in the weeks, months, and years ahead to take steps to promote diversity, equity, inclusion, and racial justice.

"The recent deaths of George Floyd, Breonna Taylor, Ahmaud Arbery, and too many others have ignited strong emotions and continue to shed a glaring light on the day-to-day experiences of Black Americans," says the statement. "Sadly, racism and discrimination are a thread that has been woven into the fabric of this country for far too long. Adding to the challenges of the global pandemic of COVID-19, which disproportionately impact communities of color, there is a greater public health crisis plaguing our country: racism and discrimination. People of color and other marginalized groups experience a continuum of systemic racism, discrimination, and injustices that result in ongoing health inequities created by numerous factors impacting social determinants of health."

The statement lists specific actions for pharmacists to take to uphold the highest standards. The actions include, but are not limited to:

1. Working together to provide opportunities to address health care disparities and strengthen affected communities.
2. Providing pharmacist, student pharmacist, and pharmacy technician education on social injustices and systematic challenges impacting health care.
3. Delivering strategies that focus on change through communications, partnerships, and solutions to address health care disparities.
4. Continuing dialogue among pharmacy organizations and stakeholders to identify and implement change.

Please also visit the Board's new web page dedicated to [Health Equity](#).

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