November 2018

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. 600 Congratulations – Executive Director's Retirement

Oregon State Board of Pharmacy Executive Director Marcus "Marc" Watt, RPh, announced his retirement, effective October 26, 2018. Marc was appointed as the executive director in 2014, after working over 41 years as a pharmacist. Under Marc's leadership the agency has been recognized nationally for its innovation, excellence, and commitment to serving the citizens of Oregon. Marc's willingness to address important safety and public health policy initiatives was critical. Initiatives during Marc's time at the Board included developing and implementing pharmacist prescriptive authority for contraceptives and naloxone, as well as creating the Public Health and Pharmacy Formulary Advisory Committee for additional prescriptive authorities; the major transitioning of pharmacists and certified pharmacy technicians to biennial licensure; the intentional automatic refilling of medications; dispensing practitioner drug outlet registration and compliance; and addressing pharmacy working conditions. For the agency, Marc spearheaded a robust customer service focus for the public and worked diligently to make internal processes more streamlined, improving efficiencies. These issues provided him with many challenging and rewarding opportunities during his service to the Board and to all Oregonians. The members of the Board and agency staff wish him all the best for his well-earned retirement!

The process to recruit and select a new director has begun. The position description and timeline were discussed at the October Board meeting. The Board is seeking public input on the recruitment for the new executive director, so public comment and input are encouraged. The Board is working to have a new candidate in place by early 2019.

No. 601 Board Member News

The Board wishes to acknowledge Public Member Sue Richardson for her service to the citizens of Oregon as she completes her time with the Board. Sue brought a fresh public member perspective to the Board. Although her time was brief, her interest in public safety and desire to understand pharmacy was at the forefront of her mind during her time on the Board this year. Key initiatives and Board accomplishments during Sue's tenure on the Board included seeing the Board's two public member positions filled after some vacancies and the development of rules for pharmacist prescriptive authority pursuant to the directives of 2017 House Bill (HB) 2397.

No. 602 Emergency Preparedness Committee – Informational

Pharmacists and technicians have important roles in meeting the medical needs of Oregonians during public health emergencies. Pharmacists can dispense preventive antibiotics or administer vaccines during disease outbreaks. Technicians can play a key role in supporting pharmacists and other volunteers in providing valuable services during an emergency. Pharmacists and technicians can assess and meet the medication needs of people displaced by storms or wildfires. By preparing now to keep family members safe and maintain critical pharmacy services during public health emergencies, they can play a crucial part in effective responses to these situations.

What is the next step? There is a new continuing education (CE) course that provides valuable background on family and business preparedness. The CE course was developed in collaboration with the Oregon State University College of Pharmacy and the Oregon State Pharmacy Association (OSPA). The five-module training provides two hours of hard-to-find law CE, plus one hour of patient safety CE, and it only costs $35! The course also presents the legal framework for pharmacy emergency response in Oregon and describes the Oregon pharmacy-public health memorandum of understanding

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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.

SAMHSA Publishes Guidance for Treating OUD

To help broaden health care professionals' understanding of medications that can be used to treat Americans with opioid use disorder (OUD), the Substance Abuse and Mental Health Services Administration (SAMHSA) offers guidance on clinical best practices in the February 2018 publication titled *Treatment Improvement Protocol 63, Medications for Opioid Use Disorder.* The publication reviews the use of the three Food and Drug Administration (FDA)-approved medications used to treat OUD – methadone, naltrexone, and buprenorphine – and other strategies and services needed to support recovery for people with OUD.

Additionally, in February 2018, SAMHSA released the publication *Clinical Guidance for Treating Pregnant and Parenting Women with Opioid Use Disorder and Their Infants,* which offers standard approaches for health care professionals. This publication provides evidence-based treatment options, including pharmacotherapy with methadone, buprenorphine, and buprenorphine/naloxone, for pregnant women with OUD. The clinical guidance also helps health care professionals and patients determine the most clinically appropriate action for a particular situation and informs individualized treatment decisions. Both publications can be found in the Publications section of SAMHSA's website at *www.samhsa.gov*.

FDA Issues Final Guidance Policy on Outsourcing Facilities

In May 2018, FDA issued a new policy designed to address any ambiguity around how to define the physical features and operations of outsourcing facilities. According to FDA Commissioner Scott Gottlieb, MD, the policy in the final guidance, *Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act,* will help to:

- ensure that compounded drugs are made under appropriate quality standards;
- provide transparency to patients and health care providers about the standards under which the compounded drugs that they purchase are made; and
- respond to stakeholder feedback requesting guidance on the meaning of "facility" under section 503B.

In the guidance, FDA explains that a section 503A establishment compounding drugs pursuant to patient-specific prescriptions may be located near or in the same building as the outsourcing facility provided that they are completely separate. As explained in the guidance, the boundaries between the section 503A establishment and outsourcing facility should be clear and may include permanent physical barriers, such as walls or locked doors, and the two operations should not share rooms, equipment, supplies, or pass-through openings (eg, they may not subdivide a room with temporary barriers such as curtains). The guidance further explains that the labeling should clearly identify the compounder who produced the drug. Lastly, the guidance reminds industry and stakeholders that all drug products compounded in an outsourcing facility are regulated under section 503B and are subject to current good manufacturing practice requirements, even if those drug products are compounded pursuant to patient-specific prescriptions. Additional information can be located at *www.fda.gov/newsevents/newsroom/fdainbrief/ucm607339.htm.*

EU-US Mutual Recognition Agreement Now Operational Between FDA and 12 Member States

In January 2018, FDA confirmed the capability of four more European Union (EU) member states – Czech Republic, Greece, Hungary, and Romania – to carry out good manufacturing practice inspections at a level equivalent to the United States. With the addition of the four EU member states, FDA can now rely on inspection results from 12 EU member states. The mutual recognition agreement between the EU and US to recognize inspections of manufacturing sites for human medicines conducted in their respective territories is progressing as planned, with plans for the agreement to be operational in all EU member states by July 15, 2019, indicates a European Medicines Agency (EMA) press release. In 2017, FDA determined the agency will recognize eight European drug regulatory authorities in Austria, Croatia, France, Italy, Malta, Spain, Sweden, and the United Kingdom as capable of conducting

inspections of manufacturing facilities that meet FDA requirements. The EMA news release, "Four more EU Member States benefit from EU-US mutual recognition agreement for inspections," can be found in the News and Events section at *www.ema.europa.eu.*

US Surgeon General Advisory Urges More Individuals to Carry Naloxone

In an April 2018 advisory, US Surgeon General Jerome M. Adams, MD, MPH, emphasizes the importance of more individuals knowing how to use naloxone and keeping it within reach. Surgeon General Adams recommends that family, friends, and those who are personally at risk for an opioid overdose keep the drug on hand. As stated in the advisory, expanding the awareness and availability of naloxone is a key part of the public health response to the opioid epidemic. The Surgeon General advisory on naloxone is part of the Trump Administration's ongoing effort to respond to the sharp increase among drug overdose deaths, notes a US Department of Health and Human Services (HHS) news release. HHS also has a website, *www.hhs.gov/opioids,* with resources and information for individuals who want to fight the opioid crisis in their communities or find help for someone in need. The advisory and news release can be found at *www.surgeongeneral.gov*.

Expanding Pharmacists' Scope of Practice Linked to Improved Cardiovascular Outcomes

Elevating pharmacy involvement in patient care and using a team-based care model are among the effective strategies for preventing cardiovascular disease that were identified in a new guide developed by the Centers for Disease Control and Prevention's (CDC's) Division for Heart Disease and Stroke Prevention (DHDSP). The guide, *Best Practices for Cardiovascular Disease Prevention Programs: A Guide to Effective Health Care System Interventions and Community Programs Linked to Clinical Services,* describes the scientific evidence behind each strategy, including collaborative drug therapy management, enabled by a collaborative practice agreement, and medication therapy management. To be included in the guide, strategies had to be supported by multiple high-quality research studies that demonstrated evidence of effectiveness in controlling blood pressure or cholesterol levels. More details about the best practice strategies along with resources and tools for implementing the strategies identified by CDC's DHDSP can be found at *www.cdc.gov/dhdsp/pubs/guides/best-practices/index.htm.*

Pharmacists Are Critical to Drug Supply Chain Integrity, States FIP

Medicines are specialized commodities and, if they are not managed rationally or appropriately, they are equivalent to a dangerous substance, indicates the International Pharmaceutical Federation (FIP). In a May 2018 report, *Pharmacists in the supply chain: The role of the medicines expert in ensuring quality and availability,* FIP provides a global picture of the role of pharmacists in supply chains, the tasks currently undertaken by pharmacists in different countries, and pharmacists' unique competencies. Based on reviews of literature, survey data, and case studies from nine countries, pharmacists were identified as having expertise that is critical to supply chain integrity. According to FIP, pharmacists and those who are involved in the planning, procurement, manufacture, storage, and distribution of medicines must:

- ♦ consider how to most effectively use the skills of the staff and personnel available;
- ♦ provide and seek training where needed; and
- ♦ keep their systems and role descriptions under review in order to adapt to changing circumstances.

FIP's report and news release can be located at *www.fip.org/news_publications.*

Emergency Department Visits for Opioid Overdoses Rose 30%

From July 2016 through September 2017, reports of emergency department (ED) visits for opioid overdoses – including prescription pain medications, heroin, and illicitly manufactured fentanyl – rose 30% in all parts of the US, according to a CDC report. The Midwest saw opioid overdoses increase 70% during this time period. According to the March 9, 2018 *Morbidity and Mortality Weekly Report*, coordinated action between EDs, health departments, mental health and treatment providers, community-based organizations, and law enforcement can prevent opioid overdose and death. People who have had an overdose are more likely to have another; thus, being seen in the ED is an opportunity for action. EDs can provide naloxone, link patients to treatment and referral services, and provide health departments with critical data on overdoses. The CDC report, "Vital Signs: Trends in Emergency Department Visits for Suspected Opioid Overdoses — United States, July 2016–September 2017," can be accessed at *http://dx.doi.org/10.15585/mmwr.mm6709e1.*

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(MOU). The MOU makes it easier for pharmacists and public health professionals to work together to meet the pharmaceutical needs of their communities during an emergency. For access to the CE and MOU, visit *www.oregonpharmacy.org/emergency-management-info*. Note: participation in this is completely voluntary and not an Oregon CE requirement for license renewal.

If you want to learn more about how to get involved with preparedness efforts in your community, here are two more options. OSPA has a standing preparedness committee chaired by Gary Miner, RPh. The group works to promote preparedness-related training for pharmacists and pharmacy technicians in Oregon – it created the new preparedness CE – and the group is working to improve connections between pharmacists and preparedness efforts around the state. To find out about meetings or learn more about this initiative, contact OSPA at *www.oregonpharmacy.org*. Another option is the State Emergency Registry of Volunteers in Oregon, the state-managed database of licensed health care professionals who volunteer in response to federal, state, and local emergencies. Licensees can sign up to be notified about various trainings and response opportunities throughout Oregon. To learn more and register, visit *https://serv-or.org*.

No. 603 An Update on Pharmacist Prescribing Authority: 2017 Oregon HB 2397

By Emad Abukhzam, 2019 PharmD Candidate, Pacific University School of Pharmacy

Pharmacists located and licensed in Oregon are gaining prescriptive authority! The Board has developed and adopted prescribing practice regulations to establish a pharmacist's authority to prescribe a drug or device via protocols that have been recommended by the Public Health and Pharmacy Formulary Advisory Committee. Oregon HB 2397 was signed into law by Governor Kate Brown on May 18, 2017. The law allows a pharmacist to prescribe post-diagnostic drugs and devices from an approved list that is generated from the statutorily-directed and governor-appointed committee, which consists of two physicians, two advanced practice nurses, and three pharmacists, who are limited to serving for two years.

The law states that an Oregon-licensed pharmacist may prescribe and dispense drugs and devices approved on the formulary set by the committee. The pharmacist is required to assess a patient prior to prescribing. A major component of the regulations is that a pharmacist will be required to document patient interaction and assessment in the form of a visit summary. Drug therapy management criteria shall be created, approved, and maintained by the pharmacist, and be based on current and referenced clinical guidelines. When considering drug therapy management, the pharmacist must:

- Include patient inclusion and exclusion criteria, and articulate explicit medical referral criteria.
- Assess subjective and objective information about the patient's health history and clinical status. The patient assessment must be performed face-to-face, in-person, and not through electronic means.
- Use the collected patient assessment information to evaluate and develop an individualized patient-centered care plan.
- Implement the care plan to include appropriate treatment goals, monitoring parameters, and follow-up.
- Provide notification to the patient's primary care provider within five business days of prescribing formulary drug therapy or medical devices.

The pharmacist must maintain all records of prescribing for a minimum of 10 years, including, but not limited to, the drug therapy management protocol, prescription record, consultation, and visit summary. A copy of the visit summary must be made available to the patient, provider, and the Board upon request. It is the pharmacist's responsibility and authority to prescribe pursuant to the formulary and protocol. The pharmacist cannot prescribe a drug or device to him or herself or to immediate family members.

The current formulary and protocol compendia include a variety of drugs and devices that a pharmacist may prescribe. A pharmacist may prescribe the continuation of therapy of an existing prescription via the drug therapy management protocol in accordance with regulations outlined by Division 20, the Board's rule regarding pharmacist prescriptive authority. The rules allow the pharmacist to prescribe any non-controlled medication to extend the patient's prescription therapy to avoid interruption of treatment. As such, the pharmacist shall only prescribe a drug quantity sufficient for the circumstance, not to exceed a 60-day supply, and no more than two extensions in a 12-month period per medication. Additionally, a pharmacist may prescribe emergency contraception.

The requirements/restrictions for prescribing by a pharmacist are limited for certain drugs.

For cough and cold symptom management a pharmacist may prescribe the following, per the outlined parameters:

1. Pseudoephedrine-containing products
   - Mandatory prescription drug monitoring program

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lookup, mandatory positive identification, and documentation

- ♦ Quantity restriction:
  - ◊ Maximum of 3.6 grams per month or 60 tablets, whichever is less
  - ◊ Yearly restriction: Maximum three times per year
- ♦ Age restriction: 18 years and older only

2. Benzonatate
   - ♦ Quantity restriction: Not to exceed a seven-day supply for cough treatment
3. Short-acting beta-agonist (albuterol)
   - ♦ Quantity restriction: One metered-dose inhaler or one box of 25 nebulizer ampules per year
4. Intranasal corticosteroids

Pharmacists may submit formulary recommendations to the committee for consideration. A pharmacist may request that additional drugs or devices be added to the formulary via a form provided by the Board. The committee will review requests and make recommendations to the Board. The Board may then consider the recommendations received and may choose to adopt them into the Division 20 rules as deemed necessary.

The legal authority provided by these new regulations is autonomous prescribing by a pharmacist, but the practical application of these processes is intended to be collaborative with the patient's care providers. It will be critical for pharmacists participating in these authorities to not further fragment care, but rather coordinate it for best patient outcomes.

Visit the Board's Public Health and Pharmacy Formulary Advisory Committee web page or attend the public sessions of meetings to stay up to date with any new information regarding this topic.

No. 604 Licensing Department and Other Updates

Effective in 2019, the Board will no longer be offering the law exam on the Board website for one hour of Oregon CE.

Effective January 1, 2019, the Federal Bureau of Investigation is implementing a $1.25 increase in the fee for the national fingerprint background check. The new background check fee will total $41.25. The national fingerprint background check is required for all applicants for individual licensure with the Board. Applications will be revised to reflect the new pricing and posted on the Board's website in late December.

Board staff has been reviewing and making updates to many of the license applications and anticipates having many of the updated applications online in early 2019, which will coincide with updates to the website. When hiring new employees or submitting applications for owner or location changes, please download the application directly from the Board's website to be sure that you are using the current version. Using an outdated application could result in a delay in licensure.

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