December 2019

Oregon State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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No. 617 Board Member News

The Oregon State Board of Pharmacy welcomes new pharmacist member, Michelle Murray RPh, BCPS, appointed by Governor Kate Brown to serve beginning July 1, 2019. Michelle graduated from Oregon State University with a bachelor of science degree in pharmacy. She completed a pharmacy residency at the Portland Veterans Affairs Medical Center and has worked in various capacities at Legacy Health for over 30 years. She has been active in the state professional society, Oregon Society of Health-System Pharmacists throughout her career, serving on several committees and the board of directors. She strongly believes in giving back to the profession of pharmacy.

No. 618 Board Member Opportunities

The Board has the following member opportunities available:

- One public member position is currently vacant. Please apply now if interested.
- Two pharmacy technician member positions are available for appointment or reappointment effective February 17, 2020. Please apply by December 10, 2019, for consideration.
- Two pharmacist member positions are available for appointment or reappointment effective July 1, 2020. Please apply by March 1, 2020, for consideration.

Each position is appointed by the governor and each Board member serves at the pleasure of the governor. The Board encourages all interested and qualified individuals to apply sooner rather than later, as the governor's office may close the applicant pool without notice. For more information, including qualifications and how to apply, please see Oregon Revised Statutes (ORS) 689.115 and visit the Board's website.

No. 619 Shared Pharmacy Services – Update

The Board is no longer approving shared services agreements for non-patient-specific compounding or repackaging/prepackaging of medication for a prescriber.

Regarding non-patient-specific human drug compounded products (including "office use"), the Board advises pharmacies to work directly with clinicians to proactively identify patient needs via the provision of patient-specific prescriptions. Another alternative is for a prescriber to contract with a 503B outsourcing facility to receive drugs for the purpose of the prescriber administering or dispensing the drugs to a patient.

Regarding health system compounding and repackaging/prepackaging for "own use" products, Food and Drug Administration (FDA) continues to provide guidance and plans to publish an updated guidance in early to mid-2020. The Board expects that a health system that compounds or prepackages for its various hospital entities retain readily accessible, clear documentation of the invoicing of drug products within its system. Additionally, licensees involved in this area of practice are encouraged to routinely review federal regulations commonly referred to as "track and trace" being promulgated pursuant to Title II of the 2013 Drug Quality and Security Act, the Drug Supply Chain Security Act.

Regarding veterinary drug compounding, on November 19, 2019, FDA issued draft Guidance for Industry #256, "Compounding Animal Drugs from Bulk Drug Substances." FDA stated that the draft guidance, "addresses situations in which, if the guidance is finalized, the FDA does not intend to take action for certain violations of the Food, Drug, & Cosmetic Act when pharmacists and veterinarians compound or oversee the compounding of animal drugs from bulk drug substances:

- to fill patient-specific prescriptions for nonfood-producing animals
- to compound "office stock" (certain drugs kept in veterinarians' supply) for nonfood-producing animals and
- to compound antidotes for food-producing animals."

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National Pharmacy Compliance News

December 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.

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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At this time, the Board recommends that any pharmacy providing non-patient specific veterinary drug compounded products to a veterinarian retain all documentation, including invoices/sales records and all related compounding records. Be prepared to identify your pharmacy's procedures and records during your annual inspection.

No. 620 Administrative Rules Proposed

At its October 2019 meeting, the Board developed a number of proposed rules in response to Oregon's 2019 legislative session bills that impact pharmacy practice and licensees. These proposed rules involve naloxone, licensure for military spouses/domestic partners, removing licensure barriers for immigrants and refugees, availability of prescription readers, and pharmacist prescribing of contraceptives.

When a pharmacist is dispensing an opioid prescription in excess of 50 morphine milligram equivalents (MMEs)/day, he or she should consider prescribing naloxone and the necessary supplies for administration to the patient. Note that this does not preclude a pharmacist from prescribing naloxone to a patient with an MME less than 50. Additionally, pharmacies providing naloxone services must provide written notice in a conspicuous manner that naloxone is available at the pharmacy.

Other proposed rules address Board policy and regulation related to expedited licensure for military spouses/domestic partners and removal of licensure barriers for immigrants and refugees.

Oregon pharmacy drug outlets shall note that the directives of 2019 House Bill 2935 become operative on January 1, 2020; this law requires a pharmacy to notify a person who is blind, visually impaired, or print disabled that a prescription reader is available to the person upon request.

Oregon pharmacists prescribing contraceptives to patients shall note that on January 1, 2020, the provision of law in ORS 689.689(1)(a)(b) is removed; this means that the requirement for a person under age 18 to provide evidence of a previous prescription from a primary care or women's health care practitioner is removed, thereby removing contraceptive prescribing age requirements, via repeal of Oregon Administrative Rules (OAR) 855-019-0420.

No. 621 Prescribing Insulin and Supplies

Did you know that an Oregon-licensed pharmacist has more professional options than ever before to identify specific patient medical needs and provide access to critical medications, such as insulin?

Governor Brown signed Senate Bill 9 into law earlier this year, permitting a pharmacist to prescribe and dispense emergency refills of insulin and associated insulin-related devices and supplies to a diabetic patient in need. Take time to read the law, as well as the administrative rule (OAR 855-019-0470) associated with this new prescriptive authority. Another legal option available to the Oregon pharmacist to appropriately manage a patient's medication needs is via continuation of therapy protocol, codified in Division 020, specifically OAR 855-020-0110 and OAR 855-020-0300(1). In each of these options, the pharmacist is the prescriber issuing the prescription.

Separate from the pharmacist prescribing identified above there is the more traditional method provided in OAR 855-041-1120(2). This regulation permits the pharmacist caring for a patient in need of medication to provide a patient with a sufficient quantity of a non-controlled drug to last until a practitioner can be contacted for authorization, up to a 72-hour supply. A pharmacist acting pursuant to this regulation is to document professional decision making when providing a patient with a medication, such as insulin, that is only available in unit-of-use packaging, which may exceed a 72-hour supply. Of course, a pharmacist may always contact a clinician to initiate a new prescription, as well as another pharmacy to initiate a transfer of a prescription, when that is the best option for the circumstances.

The Board expects pharmacists to practice as professional health care providers as Board regulations permit and require. There are a number of available options for an Oregon pharmacist to identify a patient's medication need and intentionally manage the patient; no patient should ever leave an Oregon pharmacy without access to life-saving medications, such as insulin and diabetic supplies.

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