February 2018

Oregon State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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

No. 591 Board Member News

Oregon State Board of Pharmacy Public Member Christine Chute has concluded her service to the Board. In 2010, Christine was appointed to the Board by Governor Ted Kulongoski; she was reappointed in 2014 by Governor John Kitzhaber. She brought years of service to the Board as a former Board counsel between 2002-2006. Among Christine's many noteworthy accomplishments was her work with the scheduling of pseudoephedrine in Oregon. During her time as Board counsel, Christine assisted with the development of the scheduling of pseudoephedrine, and she largely authored the temporary and permanent rules associated with that event. Her leadership with rule development and the ensuing fiscal impact statements in 2005 helped to curb the methamphetamine epidemic in our state. Christine was dedicated to representing the Board on the Governor's Advisory Committee for Driving Under the Influence of Intoxicants, and she served as a panel member at various association meetings representing the perspective of the Board from the public member's point of view. Thank you, Christine, for your many years of service to the citizens of the state of Oregon by serving as both Board counsel and public Board member.

No. 592 Medication Reconciliation and the Role of the Oregon Pharmacy Technician

The term "medication reconciliation" is defined by the Joint Commission as "the process of comparing the medications a patient is taking (and should be taking) with newly ordered medications" in order to resolve discrepancies or potential problems. This definition emphasizes the importance of reconciliation, which is the act of comparing medication lists and noting inconsistencies versus the act of merely collecting a medication history. It is nationally recommended that pharmacists be involved in functions including, but not limited to, developing policies and processes, implementing and continuously improving those processes, and training and ensuring the continuing competency of those involved in medication reconciliation. When pharmacy is involved, the Board expects a pharmacist to establish roles and responsibilities of health care providers in medication reconciliation processes, including pharmacy technicians, interns, and other medical support personnel.

When implementing a pharmacy technician medication history program, it is essential to be in compliance with Board laws and rules regarding what pharmacy technicians can and cannot do. Pharmacy technicians are not allowed to make clinical decisions, of any kind, during the medication reconciliation process or otherwise. They may write down the information gathered from the patient, gather information from a secondary source if needed, and present it to the pharmacist for verification. For example, a patient reports taking furosemide as needed based on his or her weight. However, the pharmacy technician finds that the patient's prescription has a direction for furosemide 20 mg daily. In this scenario, the pharmacy technician may not make a judgment call to include only the direction from the prescription and omit the information about how the patient is taking it. In a different scenario, a patient tells the pharmacy technician that he or she takes a medication for blood pressure at home and is unable to recall the name. The pharmacy technician then goes down the Prior to Admit medication list and picks out a drug that he or she believes is the blood pressure medication. By doing that, the pharmacy technician uses clinical judgment to identify which drug has an indication for high blood pressure, which is not within the scope of pharmacy technician duties and is not permitted by the Board.

Pharmacy technicians who perform medication history gathering must have proper training on how to collect medication history and interview a patient. Pharmacy technicians may compare the list they gather from medication history to what is currently ordered for the patient in the hospital and make note of differences when updating the patient's medical record. It is a pharmacist's responsibility to verify and review any clinical scenarios or discrepancies in the patient medical record **prior** to making prescribing decisions.

continued on page 4

National Pharmacy Compliance News

February 2018

NABPF
National Association of Boards of Pharmacy Foundation

FDA Draft Guidance Addresses Delayed Enforcement of DSCSA Requirements for Product Identifiers

Food and Drug Administration (FDA) issued a draft guidance for industry that informs manufacturers and other supply chain stakeholders that although manufacturers are to begin including a product identifier on prescription drug packages and cases on November 27, 2017, FDA is delaying enforcement of those requirements until November 2018 to provide manufacturers additional time and avoid supply disruptions. The compliance policy outlined in the June 2017 draft guidance, *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy,* applies solely to products without a product identifier that are introduced into commerce by a manufacturer between November 27, 2017, and November 26, 2018. While manufacturers work to meet product identifier requirements, they must comply with other Drug Supply Chain Security Act (DSCSA) requirements. The draft guidance can be accessed from FDA's website at *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm565358.htm.*

Amount of Prescribed Opioids Remains High, Reports CDC

The amount of opioids prescribed remains approximately three times as high as in 1999, despite reductions in each year after 2010 through 2015. Centers for Disease Control and Prevention (CDC) researchers analyzed retail prescription data to assess opioid prescribing in the United States from 2006 to 2015 and county-level prescribing patterns in 2010 and 2015. According to a CDC report, results of the study showed higher amounts of opioids were prescribed in counties that had a greater percentage of non-Hispanic white residents, a higher prevalence of diabetes and arthritis, micropolitan status (ie, town/city; nonmetro), and higher unemployment and Medicaid enrollment rates. The researchers conclude that health care providers should carefully weigh the benefits and risks when prescribing opioids outside of end-of-life care, follow evidence-based guidelines (eg, CDC's *Guideline for Prescribing Opioids for Chronic Pain*), and consider non-opioid therapy for chronic pain treatment.

Additionally, the researchers conclude that state and local jurisdictions can use these findings along with prescription drug monitoring program (PDMP) data to identify prescribing patterns that place patients at risk for opioid use disorder and overdose and to target interventions with prescribers based on opioid prescribing guidelines. The July 7, 2017 *Morbidity and Mortality Weekly Report,* "Vital Signs: Changes in Opioid Prescribing in the United States, 2006–2015," can be accessed on the CDC website at *www.cdc.gov/mmwr/index.html* in the Weekly Report section.

AMA Opioid Task Force Encourages Co-Prescribing Naloxone to At-Risk Patients

The American Medical Association (AMA) Opioid Task Force encourages physicians to consider co-prescribing naloxone when it is clinically appropriate to do so. The AMA Opioid Task Force offers several questions for determining whether to co-prescribe naloxone to a patient or a patient's family member or close friend, which may be found in the August 2017 document, "AMA Opioid Task Force naloxone recommendations," available on the AMA opioid microsite at *https://www.end-opioid-epidemic.org.*

The Naloxone section of the AMA opioid microsite also offers physicians multiple resources on co-prescribing naloxone in their practice and community. To help end the opioid epidemic, the AMA Opioid Task Force made several recommendations for physicians, including registering and using state PDMPs, training and education on evidence-based treatment, and promoting safe storage and disposal of opioids and medications.

Opioid Addiction Medications Should Not Be Withheld From Patients Taking Benzodiazepines or CNS Depressants

Opioid addiction medications – buprenorphine and methadone – should not be withheld from patients taking benzodiazepines or other drugs that depress the central nervous system (CNS), advises FDA. The combined use of these drugs increases the risk of serious side effects; however, the harm caused by untreated opioid addiction usually outweighs these risks. Careful medication management by health care providers can reduce these risks, notes a safety alert. FDA is requiring this information to be added to the buprenorphine and methadone drug labels along with detailed recommendations for

minimizing the use of medication-assisted treatment drugs and benzodiazepines together.

Health care providers should take several actions and precautions and should develop a treatment plan when buprenorphine or methadone is used in combination with benzodiazepines or other CNS depressants. Additional information may be found in an FDA Drug Safety Communication announcement at *www.fda.gov/Drugs/DrugSafety/ucm575307.htm.*

New Study Shows Substantial Variation in the Availability of Pharmacies Across the Country

Despite the rising number of US pharmacies from 2007 to 2015, the availability of pharmacies varied significantly across local areas, indicates a new study. The study, *The availability of pharmacies in the United States: 2007–2015,* found that the number of community pharmacies increased 6.3% from 63,752 to 67,753 between 2007 and 2015. Although the number of pharmacies per capita remained at 2.11 per 10,000 individuals between 2007 and 2015, the researchers found substantial variation across counties. "Some counties have 13 pharmacies per capita, while others have none," said Dima Qato, lead study author and assistant professor of pharmacy systems, outcomes and policy, in a University of Illinois at Chicago (UIC) news release.

In 2015, counties in the highest quintile had nearly three-fold more pharmacies than those in the lowest quintile. Counties in the lowest quintile are located in the Pacific West, Southwest, and Great Lakes regions, while counties with the highest tend to be located in the Northeast, Southeast, Northern Appalachia, and Plains states. The researchers conclude that future programs and policies should address the availability of pharmacies and ensure that pharmacy characteristics, including accommodations such as multilingual staffing and home delivery, align with local population needs.

To view the study, visit *https://doi.org/10.1371/journal.pone.0183172.* The UIC news release is available at *https://today.uic.edu/access-to-pharmacies-limited-to-some-patients.*

Consent Decree Entered Against Outsourcing Facility Isomeric Pharmacy Solutions

Under a consent decree of permanent injunction entered in August 2017, Isomeric Pharmacy Solutions of Salt Lake City, UT, its owners, and chief operating officer are prohibited from manufacturing, processing, packing, holding, or distributing drugs until they comply with the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its regulations, in addition to other requirements. Isomeric manufactured and distributed purportedly sterile drug products, including injectable and ophthalmic drugs, that were adulterated because the drugs were made under insanitary conditions and in violation of current good manufacturing practice requirements under the FD&C Act, according to the complaint for permanent injunction. The complaint also alleges that Isomeric manufactured and distributed unapproved drugs and drugs that were misbranded because their labeling did not bear adequate directions for use. Isomeric initially registered as an outsourcing facility in July 2015 and reregistered in December 2015 and January 2017. Additional information is available in an FDA news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm570130.htm.*

FDA Issues Warning on Alcohol Pads or Benzalkonium Chloride Antiseptic Towelettes Made by Foshan

In September 2017, FDA alerted health care providers and patients to not use alcohol pads or benzalkonium chloride antiseptic towelettes made by Foshan Flying Medical Products Co, Ltd, located in China, due to lack of sterility assurance and other quality issues. These products are distributed by Total Resources International, of Walnut, CA, and Simple Diagnostics, Inc, of Williston Park, NY. The use of these alcohol pads and antiseptic towelettes could cause infections.

FDA placed all drug products made by Foshan on import alert on May 23, 2017, to stop these products from entering the US. However, FDA is concerned these products might still be in distribution in the US. FDA also sent Foshan a warning letter on August 1, 2017, for violations of current good manufacturing practice regulations. FDA initially contacted Foshan regarding a recall on May 25, 2017, and had several follow-up meetings with the company. Foshan has not taken action to remove its alcohol pads or antiseptic towelettes from the market. The safety alert posted to FDA's website may be found at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm574576.htm.*

Pharmacies and health care facilities that have alcohol pads and antiseptic towelettes labeled by Total Resources or Simple Diagnostics should immediately stop using them and discard the products. Adverse events or side effects related to the use of these products may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/MedWatch/report.*

continued from page 1

The following frequently asked questions are provided to address pharmacy involvement in the medication reconciliation process. The Board does not have jurisdictional oversight over what functions nurses and other non-pharmacy personnel may be permitted to perform.

Q. What is medication reconciliation?

A. **Medication reconciliation (or "med rec")** is the process of creating the most accurate list possible of all medications a patient is taking – including drug name, dosage, frequency, and route – and comparing that list against the physician's admission, transfer, and/or discharge orders, with the goal of providing correct medications to the patient at all transition points within the hospital.

Q. Are pharmacy technicians allowed to perform medication reconciliation without a pharmacist oversight and review?

A. **No.** However, a pharmacy technician who has received training appropriate for the medication reconciliation process may assist in the data collection process in order to obtain the best possible medication history for the patient. Please note that while pharmacy technicians are allowed to assist in the medication reconciliation process, they **may not** do so independently. A supervising pharmacist must verify a medication history summary collected by a pharmacy technician and be available to assist the technician if requested.

A person licensed to perform the duties of a pharmacy technician may perform the duties of a pharmacy technician only under the supervision, direction, and control of a licensed pharmacist.

Q. Is a pharmacist required to verify the medication history obtained by a pharmacy technician?

A. **Yes.** A pharmacist is required to verify all medication histories obtained by pharmacy technicians in the medication reconciliation process. This task may not be delegated to non-pharmacist staff.

Q. Are pharmacy technicians allowed to make clinical decisions during the medication reconciliation process?

A. **No.** Pharmacy technicians are not allowed to make clinical decisions, of any kind, during the medication reconciliation process or otherwise. Making clinical decisions is not in the scope of the pharmacy technician's duties. If a technician makes a clinical decision, the technician, pharmacist, and outlet may be subject to discipline for engaging in the practice of pharmacy without a license.

Q. Is the verbal communication of a patient's medication history from pharmacy technician to pharmacy technician allowed? This could be a request for a patient's medical history printout from a health care provider outside of a hospital or health system, such as a patient's local pharmacy or primary care provider.

A. **Yes.** However, technician to technician communication would require verifiable documentation (ie, faxed medication history) for the pharmacist who is verifying the medication history to be able to validate the information. Clinical decisions may not be made during communications such as these.

Q. Is the communication of a patient's medical history between pharmacy technicians using disease states or medication indications allowed?

A. **No.** Pharmacy technicians **are not allowed** to communicate a patient's medication history to another pharmacy technician by discussing disease states or indications.

No. 593 Oregon Patient Safety Commission Seeking New Board Member Nominations

The Oregon Patient Safety Commission (OPSC) welcomes nominations to fill the pharmacist seat on its Board of Directors, effective October 9, 2018. Qualified individuals – pharmacists licensed under Oregon Revised Statutes Chapter 689 – may self-nominate or receive nominations from others.

Members of the OPSC Board of Directors meet in the Portland, OR vicinity every two months for two to three hours to advise OPSC staff on patient safety policy and programs. OPSC Board members volunteer their time and are appointed by the Oregon governor to serve a four-year term, with the option to reappoint for a second term. OPSC's board consists of 17 members, reflecting the diversity of facilities, providers, insurers, purchasers, and consumers who are involved in patient safety.

OPSC is a semi-independent state agency charged by the Oregon Legislature with reducing the risk of serious adverse events occurring in Oregon's health care system and encouraging a culture of patient safety. More information about OPSC is available at *oregonpatientsafety.org*.

Before applying, nominees or those wishing to nominate an individual are encouraged to contact Tom Stuebner, OPSC executive director, at tom.stuebner@oregonpatientsafety.org, or Kristina Rice-Whitlow, executive appointments manager, Office of the Governor, at kristina.rice-whitlow@oregon.gov. More information about how to apply for a governor-appointed board or commission is outlined on the How to Apply web page on the state of Oregon website.

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