August 2018

Oregon State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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No. 596 Board Member News

The Oregon State Board of Pharmacy wishes to acknowledge Pharmacist Member Kate James, RPh, as she completes her term. During her years of service, Kate brought a wealth of leadership, professional knowledge, a strong community, compounding pharmacy background, and pharmacy management experience, as well as vigilant awareness of patient safety to the Board's conversations.

Kate's key initiatives and activities while on the Board included representing the agency many times at various Lane County and Oregon State Pharmacy Association meetings, attending a number of National Association of Boards of Pharmacy® (NABP®) Annual and District Meetings, serving on the Compounding Workgroup, drafting rules for rulemaking, and assisting staff and fellow Board members as a subject matter expert. Kate was instrumental in helping to effectuate change in consensus building for the Board procedures. In addition, Kate showed off her creative side as our resident haiku queen!

During Kate's tenure and service, the Board celebrated its 125th anniversary, pharmacy technician positions were added to the Board, and the Board received the NABP 2017 Fred T. Mahaffey Award for its work on birth control prescriptive authority.

Staff and fellow Board members wish Kate all the very best in her future plans!

No. 597 Administration and Storage Errors With Launch of New Shingles Vaccine

By Candy Chau, PharmD Candidate 2019, Pacific University School of Pharmacy

Since the launch of GlaxoSmithKline's new shingles vaccine, SHINGRIX® (recombinant zoster vaccine (RZV)), the Centers for Disease Control and Prevention (CDC) and the Oregon Health Authority (OHA) have noted administration and storage errors across health care practices for this new vaccine. In clinical trials, SHINGRIX has shown greater efficacy than ZOSTAVAX® (zoster vaccine live (ZVL)), making SHINGRIX the recommended and preferred vaccine for the prevention of herpes zoster and post-herpetic neuralgia. Based on the 2018 CDC vaccination guide, SHINGRIX is recommended for healthy adults aged 50 years and older, regardless of history of shingles or previous receipt of ZOSTAVAX.

For those previously vaccinated with ZOSTAVAX, the preferred spacing for receiving SHINGRIX is at least eight weeks for patients 70 years of age and older, and at least five years for patients under 70 years of age, with the minimal acceptable spacing of eight weeks after ZOSTAVAX (see protocol).

	SHINGRIX (RZV)	ZOSTAVAX (ZVL)
Vaccine type	Inactivated recombinant	Live attenuated
Indication	Adults 50 years of age and older for prevention of herpes zoster	Adults 60 years of age and older for prevention of herpes zoster
Number of doses	2 doses (2-6 months apart)	1 dose
Route of administration	Intramuscular (IM)	Subcutaneous (SQ)
Storage	**Refrigerated, reconstituted (Do not freeze)**	**Frozen, reconstituted**

It is important to counsel patients about expected local and systemic reactogenicity prior to administering SHINGRIX, including the potential fever, chills, fatigue, muscle pain, and headache that may occur for two to three days. Pharmacists should encourage patients to complete the series, even if they experienced a grade one to three reaction to the first dose of SHINGRIX, as it does not necessarily mean a reaction will occur with the second

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National Pharmacy Compliance News

August 2018

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.

DEA Launches New Tool to Help Distributors Make Informed Decisions About Customers

In February 2018, Drug Enforcement Administration (DEA) launched a new tool to assist drug manufacturers and distributors with their regulatory obligations under the Controlled Substances Act. The agency added a new feature to its Automation of Reports and Consolidated Orders System (ARCOS) Online Reporting System, a comprehensive drug reporting system that monitors the flow of controlled substances (CS) from their point of manufacture through commercial distribution channels to the point of sale at the dispensing/retail level. This newly added function will allow the more than 1,500 DEA-registered manufacturers and distributors to view the number of registrants who have sold a particular CS to a prospective customer in the last six months.

DEA regulations require distributors to both "know their customer" and to develop a system to identify and report suspicious orders. Manufacturers and distributors have asked DEA for assistance in fulfilling these obligations and have requested ARCOS information to help them determine if new customers are purchasing excessive quantities of CS. This new tool will provide valuable information for distributors to consider as part of their assessment. More details are available in a news release at *www.dea.gov/divisions/hq/2018/hq021418.shtml.*

PTCB Launches Certified Compounded Sterile Preparation Technician Program

In January 2018, the Pharmacy Technician Certification Board (PTCB) launched the PTCB Certified Compounded Sterile Preparation Technician (CSPT) Program. To be eligible to apply, a technician must:

- Be a PTCB certified pharmacy technician (CPhT) in good standing; and
- Have completed either a PTCB-recognized sterile compounding education/training program and one year of continuous full-time compounded sterile preparation work experience, or three years of continuous full-time compounded sterile preparation work experience.

To earn CSPT Certification, eligible CPhTs are required to pass the CSPT Exam and submit competency attestation documentation from a qualified supervisor. The two-hour, 75-question CSPT Exam covers hazardous and nonhazardous compounded sterile products in the four domains of:

- Medications and components (17%);
- Facilities and equipment (22%);
- Sterile compounding procedures (53%); and
- Handling, packaging, storage, and disposal (8%).

The purpose of the Attestation Form is to document the candidate's completion of required training and certain skill and competency assessments in such areas as aseptic technique, equipment cleaning, and use of personal protective equipment. More details about the CSPT Program are available on PTCB's website at *www.ptcb.org.*

DEA Enables Mid-level Practitioners to Prescribe and Dispense Buprenorphine

In January 2018, DEA announced a deregulatory measure that will make it easier for residents of underserved areas to receive treatment for opioid addiction. Nurse practitioners and physician assistants can now become Drug Addiction Treatment Act-Waived qualifying practitioners, which gives them authority to prescribe and dispense the opioid maintenance drug buprenorphine from their offices. This final rule took effect January 22, 2018. More details about DEA's amendments are available in a Federal Register notice titled "Implementation of the Provision of the Comprehensive Addiction and Recovery Act of 2016 Relating to the Dispensing of Narcotic Drugs for Opioid Use Disorder" (Document Number: 2018-01173).

New CDC Training Offers CPE on Antibiotic Stewardship

The Centers for Disease Control and Prevention's (CDC's) Office of Antibiotic Stewardship is offering free continuing education opportunities for health care professionals. Focused on judicious antibiotic prescribing and antibiotic resistance, the online training is offered in four sections, each with multiple modules. Section 1 of the "CDC Training on Antibiotic Stewardship" is open now and can be accessed at *www.train.org/cdctrain/course/1075730/compilation*. Additional sections will be released throughout 2018. More information and resources about CDC's national effort to help fight antibiotic resistance and improve antibiotic prescribing and use are available on CDC's website at *www.cdc.gov/antibiotic-use/index.html.* CDC is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education (CPE). This program meets the criteria for 0.258 CEUs of CPE credit. The ACPE Universal Activity Number is 0387-0000-18-031-H05-P.

Walmart to Provide Free Solution to Dispose of Medications With Schedule II Prescriptions

In partnership with Walmart, DisposeRx will provide a safe and easy way to neutralize unused, unwanted, or expired prescription opioids. DisposeRx developed a powdered product, also called DisposeRx, that permanently dissolves when mixed with water and sequesters excess opioids and other

drugs in a stiff, biodegradable gel that can be safely thrown in the trash. Walmart will provide a free packet of DisposeRx with every new Schedule II prescription filled at its 4,700 pharmacies nationwide. "This partnership with DisposeRx is an exciting opportunity for Walmart to protect the safety of its customers and public health. Unwanted or expired prescription medications left inside consumers' medicine cabinets can be an easy source for those seeking to misuse or abuse a prescription drug," said Pharmacy Clinical Services Manager for WalMart Health and Wellness and NABP Past President Jeanne D. Waggener, RPh, DPh. "We're not just making it easy for patients to safely dispose of their medications, but we're also helping prevent abuse before it starts." Additional information is provided in a January 17, 2018 news release titled "Walmart Launches Groundbreaking Disposal Solution to Aid in Fight Against Opioid Abuse and Misuse."

ASHP Research and Education Foundation Predicts Trends to Affect Pharmacy in 2018

In the 2018 Pharmacy Forecast: Strategic Planning Advice for Pharmacy Departments in Hospitals and Health Systems, the American Society of Health-System Pharmacists (ASHP) Research and Education Foundation provides guidance on eight topics that will challenge pharmacy practice leaders in hospitals and health systems. Published in the January 15, 2018 issue of American Journal of Health-System Pharmacy, the new report focuses on the following areas:

- Therapeutic innovation;
- Data, analytics, and technology;
- Business of pharmacy;
- Pharmacy and health-system leadership;
- Advanced pharmacy technician roles;
- Population health management;
- Public health imperatives; and
- Coping with uncertainty and chaos.

The 2018 report is available at *www.ajhp.org/content/75/2/23.*

USP Encourages Pharmacists to Help Patients Find Quality Dietary Supplements

Recall announcements, enforcement actions, and reports challenging the quality of dietary supplements are problematic issues facing pharmacists who want to ensure that the over-the-counter (OTC) products they are recommending to patients are of good quality. Many consumers purchase OTC dietary supplements and herbal products, often assuming they are regulated like prescription medications. While the law requires pharmaceuticals to meet specific quality standards set by the United States Pharmacopeial Convention (USP), the same requirements do not apply to supplements. For this reason, USP has created quality standards and a verification process specifically for these health products. Brands displaying the USP Verified Mark signal to the public that "what's on their label is what's in the bottle." Health care practitioners can learn more about USP's efforts at *www.usp.org/dietary-supplements-herbal-medicines.*

Further, USP Dietary Supplement Verification Services are available to manufacturers and brands worldwide. They include Good Manufacturing Practice facility auditing, product quality control and manufacturing product documentation review, and product testing. Manufacturers that are participating in USP's verification program for dietary supplements can be found at *www.usp.org/verification-services/program-participants.*

New CPE Monitor Subscription Plan Helps Pharmacists Track Compliance Via Mobile App

To help pharmacists easily monitor their CPE compliance, NABP partnered with the Accreditation Council for Pharmacy Education (ACPE) to develop CPE Monitor Plus, a subscription service for CPE Monitor®. Launched in April 2018, the new subscription service enables pharmacists to perform a variety of advanced functions beyond the basic CPE Monitor service, including:

- viewing CPE credit status by state to verify at a glance how much CPE credit must be earned to satisfy license renewal requirements;
- uploading certificates from non-ACPE CPE courses and applying them to relevant state licenses;
- receiving email alerts when CPE cycle deadlines are approaching;
- viewing all transcripts and individual courses and generating simplified, automated reports;
- searching for additional ACPE activities via ACPE P.L.A.N. (Pharmacists' Learning Assistance Network); and
- accessing ACPE CPD (Continuous Professional Development) via single sign on.

CPE Monitor Plus is available for an annual, renewable subscription fee of $29.95, regardless of how many licenses a pharmacist has or adds at a later date. CPE Monitor Plus is only available via NABP's new mobile app. Search for NABP e-Profile in Google Play Store (Android) or the App Store (iPhone).

The standard CPE Monitor service is still available for free and can also be accessed via the app or a desktop by signing in with NABP e-Profile login credentials.

For more information, visit *www.nabp.pharmacy/CPE.*

CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their CPE credit electronically

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dose. Although the second dose of the series should be administered two to six months apart from the initial dose, the vaccine series does **not** need to be restarted if more than six months have elapsed. However, patients should be educated that risk may remain during a longer than recommended interval between doses.

To access Oregon's SHINGRIX and other state immunization protocols, please visit *www.oregon.gov/oha/ph/preventionwellness/vaccinesimmunization/immunizationproviderresources/pages/pharmpro.aspx.*

No. 598 Expiration Dates

Oregon Revised Statute 689.505(5) states that "[a] pharmacist or pharmacy intern shall not dispense, on the prescription of a practitioner, any drug without affixing to the container thereof a clear and legible label. The label may be printed or written" and shall state "an expiration date after which the patient should not use the drug." In addition, Oregon Administrative Rule 855-041-1130(1)(j) states that prescriptions must be labeled with "[a]n expiration date after which the patient should not use the drug or medicine. Expiration dates on prescriptions must be the same as that on the original container unless, in the pharmacist's professional judgment, a shorter expiration date is warranted. Any drug bearing an expiration date shall not be dispensed beyond the said expiration date of the drug."

Expiration dates are a fact of life in all facets of the pharmacy profession. It is the date that a pharmaceutical manufacturer assigns, pursuant to stability and other studies, to assure the public of safe and effective drug product. The public depends on pharmacists, as well as the entire chain of medication distribution, to be handling and dispensing products that are of assured quality and safety.

Each pharmacy should take time to reassess their policies and procedures related to expiration dates. For example, many pharmacy computer systems utilize a default one-year expiration date from the date a medication is being filled for the vial's prescription label. While this practice is common, it can set up a pharmacist to inadvertently misbrand a dispensed prescription. When a stock bottle of medication being used to fill a patient's prescription has an expiration date of less than one year from the date of filling, and the system affixes a (default) date of one year from the date of filling, this circumstance may result in a misbranded product being dispensed to the patient, if the date is not changed or corrected. If this occurs, it becomes clear that the safety implication is that it may be possible for a patient to continue taking a drug beyond its expiration date.

When a pharmacy has a robust system in place to routinely check inventory, clearly mark close-to-expiration and short-dated products, and pull all expired products, they will be more reasonably assured that they will not be processing and dispensing any medications for use beyond expiration dates.

No. 599 Oregon Health Plan – Provider Enrollment Deadline

Attention all Oregon pharmacists who provide immunizations and prescribing services to patients: starting September 1, 2018, OHA will only pay for pharmacy claims when they include the National Provider Identifier of an OHA-enrolled prescriber. This applies to paper, point of sale, and provider web portal claims billed to OHA, as well as all pharmacy claims reported to OHA by coordinated care organizations.

This means that by September 1, any providers who write prescriptions for Oregon Health Plan (OHP) members must enroll with OHA, including certified pharmacists who administer vaccines or prescribe birth control to members. This process will ensure state compliance with federal Medicaid program integrity regulations.

Pharmacists who prescribe services and medications, such as birth control, and who prescribe and administer vaccines to any OHP patients must enroll with OHA by August 31, 2018. Instructions are available on the OHP Provider Enrollment web page at *www.oregon.gov/oha/HSD/OHP/Pages/Provider-Enroll.aspx.*

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.

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