April 2016

News

Washington State Pharmacy Quality Assurance Commission

Published to promote compliance of pharmacy and drug law

Dept. of Health • PO Box 47852 • Olympia, WA 98504-7852
www.doh.wa.gov/LicensesPermitsandCertificates/ProfessionsNewReneworUpdate/PharmacyCommission.aspx

No. 1223 New Commission Members – Appointed January 28

Jerrie Allard – Public Member

Jerrie Allard resides in Nine Mile Falls, WA, a small community northwest of Spokane, WA. She is a graduate of Eastern Washington University, where she earned a bachelor of arts degree in interdisciplinary studies and graduated with honors and as a recipient of the dean's honor student award. After a 20-year career in government and nonprofit administration, Jerrie retired in 2015 to enjoy a slower pace of life and to travel with her husband of 40 years. She has since established a consulting business, working with clients on projects such as accountable communities of health and oral health. Jerrie has served in leadership roles on a number of boards, including Aging and Long Term Care of Eastern Washington, Washington Information Network 2-1-1, and the Federal Emergency Management Agency Emergency Food and Shelter Board in Spokane.

Kenneth Kenyon – Pharmacist

Ken Kenyon, PharmD, BCPS, received his doctor of pharmacy degree from the University of Maryland School of Pharmacy and completed two years of post-graduate residency training at the Medical University of South Carolina. In 2003, Ken relocated to Washington to take a position as a cardiology clinical pharmacist at the University of Washington (UW) Medical Center. Ken is the director of pharmacy at UW Medicine – Valley Medical Center and is a clinical associate professor with the UW School of Pharmacy.

Teri Ferreira – Pharmacist

Teri Ferreira, RPh, is the general manager for Consonus Pharmacy, which provides pharmacy services to more than 5,000 nursing home and assisted living residents in the state. After graduating with a bachelor of pharmacy degree from Washington State University in 1991, Teri gained extensive professional experience in both retail and long-term care pharmacy positions. Teri is a past president of the Washington State Pharmacy Association, where she continues to be actively involved. She is also actively involved with the Washington Health Care Association, LeadingAge Washington, and the American Society of Consultant Pharmacists.

No. 1224 Appointment of Interim Executive Director

Steven Saxe, RPh, FACHE, has been appointed interim executive director for the Washington State Pharmacy Quality Assurance Commission. Steve began working with the Washington State Department of Health as the executive director for the Washington State Board of Pharmacy in 2004 when Don Williams retired. Over the years, Steve held additional office director positions at the department, still working with the Board and staff. Most recently, he directed the Office of Community Health Systems. Steve is a graduate of Washington State University College of Pharmacy and completed an American Society of Health-System Pharmacists hospital pharmacy residency. He also has a master of health care administration from Duke University and is board certified in health care management. Before joining the Department of Health, Steve worked in both clinical pharmacy and health care administration positions in North Carolina, California, and Washington.

No. 1225 Secure and Responsible Drug Disposal

At the March 3, 2016 Commission meeting, Commission members decided that Washington State pharmacies no longer need to obtain Commission approval to participate in a secure and responsible drug disposal program (more commonly known as drug take-back). Washington Administrative Code (WAC) 246-869-130(4) allows controlled substances (CS) to be returned to a pharmacy for destruction in accordance with Drug Enforcement Administration (DEA) regulations. DEA published its final ruling on the Secure and Responsible Drug Disposal Act on

Continued on page 4

FDA Approves Naloxone Nasal Spray to Prevent Opioid Overdose Deaths

Food and Drug Administration (FDA) has approved Narcan® Nasal Spray (also known as naloxone), a life-saving medication that can stop or reverse the effects of an opioid overdose. Prior to this approval, naloxone was only approved in injectable forms, most commonly delivered by syringe or auto-injector, explains FDA in a news release.

Narcan Nasal Spray does not require assembly and delivers a consistent, measured dose when used as directed. This prescription product can be used on adults or children and is easily administered by anyone, even those without medical training. The drug is sprayed into one nostril while the patient is lying on his or her back, which can be repeated if necessary. However, it is important to note that it is not a substitute for immediate medical care, and the person administering Narcan Nasal Spray should seek further immediate medical attention on the patient's behalf. The use of Narcan Nasal Spray in patients who are opioid dependent may result in severe opioid withdrawal characterized by body aches, diarrhea, increased heart rate (tachycardia), fever, runny nose, sneezing, goose bumps (piloerection), sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure. Narcan Nasal Spray is distributed by Adapt Pharma, Inc, of Radnor, PA. The FDA news release is available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm473505.htm.*

Selected Medication Safety Risks to Manage in 2016

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. *ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

It is a nearly impossible task to list all the risks associated with medication use that could lead to harmful medication errors. So where do health care professionals start to improve medication safety? Most people frequently resort to playing "whack-a-mole," addressing risks only after they pop up and become visible after an adverse event.

Listed below are two serious medication safety risks that might fall off the radar screen unless an adverse event happens to draw attention to them. Additional serious risks will be published in future issues of the National Association of Boards of Pharmacy® *National Pharmacy Compliance News.*

Patient Information – Placing Orders on the Wrong Patient's Electronic Health Record

A potentially hidden vulnerability that can lead to serious errors is placing orders on the wrong patient's electronic health record. A recent study published in the *Journal of the American Medical Informatics Association* identified and quantified close calls that would have resulted in wrong-patient errors. According to this study, about 14 wrong-patient electronic orders are placed every day in a large hospital system with approximately 1,500 beds, or about 68 wrong-patient errors per 100,000 medication orders. By this measure, one in 37 hospitalized patients will have an order placed for them that was intended for another patient.[1]

These errors are sometimes due to juxtaposition but more often caused by interruptions and having more than one patient's electronic health record open.

Multiple studies have demonstrated ways to reduce these events. Requiring verification of the patient's identity has reduced errors by 16% to 30%, and requiring re-entry of the patient's identification has reduced errors by 41%.[1,2] Prompting clinicians for an indication when certain medications are ordered without an indication on the patient's problem list has intercepted errors at a rate of 0.25 per 1,000 alerts.[3] In one study, most emergency department (ED) staff (81%) felt a room number watermark on the patient's electronic health record would eliminate most wrong-patient orders in the ED.[4]

Communication About Drug Therapy – Confusing the Available Concentration as the Patient's Dose on Electronic Records

Another risk deals with how home medications appear on computer screens. For example, a physician accidentally ordered 100 units of Lantus® (insulin glargine) instead of the correct dose of six units because the list of medications used at home displayed the concentration right next to the drug name on the first line, and the patient's dose below it on the second line: "Insulin glargine (Lantus) 100 units/mL," followed on the next line with "6 units subcutaneous daily every evening."

Now that insulin is available in 100 units/mL, 200 units/mL, 300 units/mL, and 500 units/mL concentrations, the risk

of receiving an overdose of insulin is high if the presentation of the order lists the product's concentration before the patient's dose. ISMP's recommendation is to list the drug name, patient-specific dose, and directions for use on the first line of the electronic medication administration record and patient medication lists, and the available concentration and any directions on how to measure the patient's dose below it.

References

1. Adelman JS, Kalkut GE, Schechter CB, et al. Understanding and preventing wrong-patient electronic orders: a randomized controlled trial. *J Am Med Inform Assoc*. 2013; 20(2):305-310.
2. Green RA, Hripcsak G, Salmasian H, et al. Intercepting wrong-patient orders in computerized provider order entry system. *Ann Emerg Med*. 2015; 65(6):679-686.
3. Galanter W, Falck S, Burns M, Laragh M, Lambert BL. Indication-based prescribing prevents wrong-patient medication errors in computerized provider order entry (CPOE). *J Am Med Inform Assoc*. 2013; 20(3):477-481.
4. Yamamoto LG. Reducing emergency department charting and ordering errors with a room number watermark on the electronic medical record display. *Hawaii J Med Public Health*. 2014; 73(10):322-328.

FDA Provides Training Videos on MedWatch Resources and Breakthrough Therapy

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the January 2016 Drug Info Rounds video, "MedWatch Tips and Tools," pharmacists discuss reporting adverse events to FDA's MedWatch Safety Information and Adverse Event Reporting Program and the resources available for health care professionals to report safety information. In the December 2015 Drug Info Rounds video, "Breakthrough Therapy," pharmacists discuss the breakthrough therapy designation program, which is intended to expedite the development and review of drugs for serious or life-threatening conditions. Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.*

Reading Medicine Labels Helps Reduce Acetaminophen Overdoses

The Acetaminophen Awareness Coalition (AAC) reminds pharmacists and other health care providers to encourage patients to properly read medicine labels to avoid unintentional acetaminophen overdoses. The coalition also encourages pharmacists and other health care providers to talk to their patients about medicine safety and acetaminophen use.

AAC's "Know Your Dose" campaign reminds patients to take these four steps to avoid acetaminophen overdose:

(1) Always read and follow the medicine label.
(2) Know if their medicines contain acetaminophen.
(3) Take only one medicine at a time that contains acetaminophen.
(4) Ask their health care provider about any questions.

Additionally, pharmacists may download or order free educational materials, including posters, flyers, and talking points, to give their patients on the Know Your Dose website at *www.knowyourdose.org.*

Over-the-Counter Children's Medicine Recalled Due to Incorrect Dose Markings

In January 2016, Perrigo Company voluntarily recalled two lots of children's guaifenesin grape liquid cough medicine (100 mg/5 mL) and three lots of children's guaifenesin DM cherry liquid cough medicine (100 mg guaifenesin and 5 mg dextromethorphan HBr/5 mL) sold in 4 oz bottles. The recall was initiated because some packages contain an oral dosing cup with incorrect dose markings. The affected products were sold by distributors nationwide and distributed through retail stores. The recalled lots and store brands are available in the Perrigo press release posted on the company's website, *www.perrigo.com,* under "Investors." To date, the company has not received reports of overdose. Distributors and retailers that have the affected lots should stop distribution and return the product using the information provided in the press release.

Adverse reactions or quality problems may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/MedWatch.*

FDA Offers Webinars on Online Drug Information Resources for Students and Clinicians

FDA's Division of Drug Information, CDER, presents a series of continuing education webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Past topics have included "Introduction to FDA's MedWatch Adverse Reporting Program" and "An Overview of the FDA's Breakthrough Therapy Designation Program." Upcoming webinars, previous webinars, and presentation slides can be accessed on FDA's website at *www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm*.

Continued from page 1

September 9, 2014. This is under Title 21 Code of Federal Regulations §1317. DEA permits ultimate users lawfully possessing household pharmaceutical non-CS and pharmaceutical CS to dispose of these drugs at authorized collection sites.

The Commission further approved a Secure and Responsible Drug Disposal Program Guidance Document, designed as a tool to assist pharmacists and to outline appropriate steps for the following Washington State entities to become DEA authorized collectors:

1. Retail pharmacies;
2. Hospitals and clinics with on-site pharmacies; and
3. Long-term care facilities that the retail or hospital and clinic pharmacies choose to register as collection sites.

Each entity participating in a secure and responsible drug disposal program is responsible for ensuring that it fully complies with all DEA regulations. This document is intended as a resource and overview but cannot be relied upon or used as a substitute for ensuring that each entity is aware of and compliant with all DEA regulations.

The Commission asks that each entity licensed under its authority to participate in a drug disposal program complete the Notice of DEA Authorized Collector Status Form (which accompanies the guidance document) and submit it to the Commission. Once the form is received, names of pharmacies participating in drug disposal programs will be posted to the Commission website.

No. 1226 Promethazine With Codeine Alert

Department of Health pharmacy investigators report a recent rise in forged prescriptions for promethazine with codeine. Promethazine with codeine, a Schedule V CS, has been used for years as a cough medication. Abusers commonly refer to it as "purple drank." "Purple drank" is a combination of promethazine with codeine mixed with a carbonated soda, such as Sprite or Mountain Dew, and candy, such as crushed Jolly Ranchers, mixed in for additional flavor.

The Commission has seen an increase in forged prescriptions for promethazine with codeine, and pharmacists have unknowingly filled them across Washington State in recent months. Pharmacists should be on the alert for promethazine with codeine prescriptions and perform due diligence in confirming that the prescription is legitimate. Look for common red flags such as a prescription being presented right before closing, an out-of-the-area prescriber you do not recognize, a patient you do not recognize, a large quantity or exact quantity for "473 mL," or a cash-paying patient you do not know.

No. 1227 Update – 2016 Legislative Session

The Washington State Legislature was unable to reach an agreement on the 2016 supplemental budget during its regular 60-day session. Governor Jay Inslee announced the immediate start of a 30-day special session and vetoed 27 of the 37 Senate bills. The Commission will post updates on enacted bills as they occur to its pharmacy law web page.

- **Substitute Senate Bill 6421 –** The bill allows health care practitioners with prescriptive authority to prescribe epinephrine autoinjectors in the name of authorized entities and dispensed by pharmacists, advanced registered nurse practitioners, and physicians. Authorized entities include but are not limited to: restaurants, recreation camps, youth sports leagues, and amusement parks. People who have completed required training may provide epinephrine autoinjectors for use by individuals experiencing anaphylactic shock. The bill requires injectors to be stored in a location readily accessible in an emergency and in accordance to manufacturer instructions. It provides immunity to the authorized entity and prescribing practitioner for any injuries or related damages from administration of the drug.

No. 1228 Application for Utilization of Ancillary Personnel – Pharmacy Technicians and Assistants

On March 3, 2016, the Commission adopted a new intake and approval process for ancillary utilization plans (AUPs) to comply with RCW 18.64A.060.

Process for New License Applications With AUPs

New pharmacy license applications, with a pharmacy AUP, must be submitted 60 days before a regularly scheduled Commission business meeting to one of the following addresses.

With check or money order

Washington State Pharmacy Quality Assurance Commission
PO Box 1099
Olympia, WA 98507-1099

Documents only (no check or money order included)

Washington State Pharmacy Quality Assurance Commission
PO Box 47877
Olympia, WA 98504-4877

Applications with AUPs submitted less than 60 days before the Commission business meeting will not be placed on the business meeting agenda until the following business meeting of the Commission. A separate request for specialized functions listed in WAC 246-901-035 is required. Specialized functions requests must include the policies and procedures, training plan, quality assurance process, and qualification to train and perform the specialized functions (WAC 246-901-100).

Process for Existing AUPs

All existing AUPs must be resubmitted for review and approval by the Commission based on a schedule the Commission establishes. The Commission will notify existing pharmacies when they should submit their AUPs

Continued on page 5

Continued from page 4

for approval. Pharmacies may continue to operate under their existing AUPs until and unless they are notified otherwise by the Commission. If pharmacies received prior approvals for their specialized functions, they should also resubmit the specialized functions when submitting their AUPs for approval by the Commission so that the Commission can review and approve the AUPs and specialized functions together. Upon Commission approval of new and existing AUPs, pharmacies will receive an approval letter from the Commission.

No. 1229 Who Can Prescribe

In Washington, providers in some professions may prescribe drugs. Providers in other professions may administer drugs ordered by an authorized prescriber. Providers in still other professions may not prescribe, administer, or dispense drugs at all. As a practicing pharmacist, do you know which profession can or cannot do which activity? For example, "Which profession must write a 'TX' following the license number on all prescriptions, is not able to prescribe oral steroids, can write only for Schedule III-V CS prescriptions, and is limited to seven days per single condition?" Is the profession an osteopathic physician, an optometrist, or a podiatric physician? If you answered "optometrist," you are correct. These practitioners must meet certification requirements to receive prescriptive authority, and their prescriptions must be within their scope of practice. In addition, effective July 24, 2015, optometrists licensed under Chapter 18.53 RCW may prescribe hydrocodone combination products in Washington. The applicable RCW/WAC where you would find the descriptive information about this profession's prescriptive authority are Chapter 18.53 RCW, WAC 246-851-580, and WAC 246-851-590.

How about a chiropractor or a chemical dependency professional? Can they prescribe, administer, or dispense drugs in Washington State? The answer for each of these professions is "no." Neither profession may prescribe, administer, or dispense drugs as described in Chapter 18.250 RCW and Chapter 18.25 RCW, respectively. For a complete table of professions within Washington State and their corresponding level of prescriptive authority, please visit the Commission website and select Who Can Prescribe and Administer Prescriptions from the sidebar. Specific details about each profession are noted along with associated RCW/WAC reference information under the "More Resources" section of the home page and may be printed for future reference.

No. 1230 Commission Recruits for 2017 Member Vacancies

The Commission is looking to fill positions for two pharmacists, one pharmacy technician, and one public member. This recruitment is to fill positions that will become vacant effective January 2017.

Public member applicants may not have any affiliation with any aspect of pharmacy. Pharmacist members must be licensed pharmacists duly licensed in Washington State for five consecutive years immediately preceding their appointment.

The governor is the appointing authority for Commission members. The Washington State Senate confirms members. People interested in appointment must be citizens of the United States and residents of this state. To apply, visit Governor Inslee's web page. For more information on qualifications or for answers to questions regarding roles and responsibilities, please visit the Commission's web page or contact the Commission office at 360/236-4834 or at wspqac@doh.wa.gov. Recruitment closes August 1, 2016.

No. 1231 Farewell to Dan Rubin

The Commission and Department of Health extend their thanks to Dan Rubin for his outstanding service to the Commission and to the patients in Washington State. Dan has been a tireless advocate for patients and access to pharmacy care. Dan provided strong leadership to the Commission as vice chair and as chair of the Business Practices subcommittee. The members and program staff will miss him.

No. 1232 Staff Changes

Chris Humberson, former executive director of the Commission, has accepted a new assignment as a pharmacy investigator with the Department of Health. The Commission wishes him the best on his transition and looks forward to his contributions in his new role.

The *Washington State Pharmacy Quality Assurance Commission News* is published by the Washington State Pharmacy Quality Assurance Commission 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.

Steven Saxe, RPh, FACHE - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Deborah Zak - Communications Manager