



# Oregon State Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

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

## **No. 538: New Board Member and New Pharmacy Inspector Introductions**

The Oregon State Board of Pharmacy welcomes pharmacist **Kate James, RPh, FIACP**, to the Board. Kate was appointed by the governor and confirmed by the Oregon Legislative Senate Rules Committee. Her appointment began July 1, 2014, and runs until June 30, 2018. Kate received her pharmacy degree from Oregon State University College of Pharmacy, and is a compounding pharmacist and owner/president of Broadway Apothecary Compounding Pharmacy in Eugene, OR. In 2008, her pharmacy was one of the first in the nation to achieve accreditation by the Pharmacy Compounding Accreditation Board. Kate is active in a number of professional organizations such as the Pain Society of Oregon, Oregon State Pharmacy Association, American Pharmacists Association, and the International Academy of Compounding Pharmacists (IACP). Her other honors and awards include the designation of fellow from the IACP in 2012. In addition to her pharmacy contributions, she is also a board member for the Science Factory Children's Museum and the Pain Society of Oregon. Kate's knowledge and experiences are a welcome addition to the Board.

The Board also welcomes its newest pharmacy inspector, **Brianne Cooper, RPh**. Brianne joined the Board in February 2014. She is a 2009 graduate of the University of the Sciences Philadelphia College of Pharmacy. Brianne worked primarily in retail prior to moving to Oregon and is excited to be living in the great northwest. In her free time, she enjoys hiking and loves to cook.

## **No. 539: Certified Pharmacy Technician License Renewal**

A reminder to all: the Board is in the midst of the Certified Oregon Pharmacy Technician license renewal cycle. Renewal notices were mailed the first week of July. If for some reason you did not receive your 2015 renewal, you can still go online and renew at [www.pharmacy.state.or.us](http://www.pharmacy.state.or.us) and click on the renewal link. If necessary, you can update your address online when completing your renewal. Remember, the renewal is done online and a delinquent fee applies to applications received or postmarked after August 31, 2014. A technician must be compliant with continuing education

and active national certification requirements prior to completion of the renewal in order to honestly attest to the moral turpitude questions.

## **No. 540: Oregon Immunizations**

It is that time of year again – the 2014-2015 flu season is upon us. August is a good time each year to review your pharmacy's policies and procedures relating to immunization practices. The Board's compliance department shares the following thoughts for your consideration, and may be reached for inquiries at 971/673-0001 or via e-mail at [pharmacy.board@state.or.us](mailto:pharmacy.board@state.or.us).

- ◆ **Confirm the Credentials of All Your Immunizing Pharmacists and Interns:** Have they successfully taken the certification training? Are they familiar with this year's protocols and expectations? (Note: Do not administer the flu vaccine prior to this year's protocol being issued.) Do they have active CPR certification? Board inspectors will look for evidence of this documentation for every vaccinator at your pharmacy. Remember that the minimum requirement for CPR certification is participation in a program that contains a hands-on training component, and is retaken at least every three years. A photocopy of each vaccinator's current CPR card is sufficient.
- ◆ **Evaluate Your "E-kit":** The immunization protocol entitled "Guidelines for Treatment of Severe Adverse Events" was written to remind us that emergency situations can, in fact, occur when administering a drug to a patient, and we as health care professionals must be prepared to act in such an event. The protocol specifically states that you must have items such as epinephrine, diphenhydramine, and smelling salts stored as an emergency kit (e-kit). The properly stocked e-kit expedites access to the contents, thereby reducing the time to assemble them in an emergency. Remember that because the e-kit contains prescription medication, it must be stored properly in the pharmacy. The protocol also requires a printed copy of the protocol to be with the emergency supplies. The inspector will check for a complete e-kit and compliance with these requirements.
- ◆ **Assess Your Pharmacy's Vaccine Storage Area:** Oregon Administrative Rule 855-019-0290(5) states

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## New Educational Video for Pharmacists Addresses Prescription Drug Abuse

The National Association of Boards of Pharmacy® (NABP®) and the Anti-Diversion Industry Working Group (ADIWG), a consortium of pharmaceutical manufacturers and distributors of controlled substances (CS), have released an educational video for pharmacists to help them identify the warning signs of prescription drug abuse and diversion when dispensing CS prescriptions. The video, entitled “Red Flags,” encourages pharmacists to help combat this national problem by exercising their professional judgment to ensure that the prescriptions they dispense were written for a legitimate medical purpose, and to act upon any unusual behavior they observe.

Drug Enforcement Administration and various state pharmacy boards have described “red flags” as circumstances surrounding the presentation of a CS prescription that should raise reasonable suspicion about the validity of that prescription. The video highlights a number of these potential warning signs, some of which are not easy to spot, by weaving personal narratives with interactions between pharmacists and customers.

The video is available in the Pharmacists section of the AWARE<sub>x</sub>E® Prescription Drug Safety website at [www.AWARERX.ORG/pharmacists](http://www.AWARERX.ORG/pharmacists).

## Root Causes: A Roadmap to Action

 *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!<sup>®</sup> Community/Ambulatory Care Edition by visiting [www.ismp.org](http://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 Error Reporting Program Report online at [www.ismp.org](http://www.ismp.org). E-mail: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org).*

Errors are almost never caused by the failure of a **single** element in the system. More often, there are **multiple** underlying system failures that lead to an error, many of which can be identified when the involved health care providers take the time to uncover them.

Consider the following error: A doctor sent a hand-written order for carbamazepine 400 mg twice daily for an adult patient with a history of seizures.

The pharmacist entered the medication into the profile of a four-year-old child with the same last name as the adult patient for whom the medication had been prescribed.

The pharmacist failed to notice that the patient was a child, as age was not in a prominent location on the order entry screen. The nurse failed to recognize that the dose was too high and administered 400 mg of carbamazepine to the child. She also never thought to question why the pharmacy would send oral tablets for a four-year-old child, considering that the drug is available in chewable tablets and as a liquid suspension.

The nurse **assumed** that the child was receiving the medication because he had a history of seizures. However, the nurse did not check the patient’s medical record. In fact, the child did **not** have a history of seizures.

The parents had a very limited understanding of English, so they were unable to intervene to correct the erroneous seizure history.

The error was finally detected after the child became lethargic and developed nausea and vomiting. At the time of discovery, the child’s carbamazepine level was 18 mcg/mL; levels greater than 12 in pediatric patients are supratherapeutic.<sup>1</sup>

It may be discouraging to see how many things go wrong when a medication error reaches a patient. However, a thorough root cause analysis (RCA) can uncover the latent failures and produce an action plan to avoid future errors.

ISMP, through a generous grant from the National Association of Boards of Pharmacy Foundation™, has developed the *Root Cause Analysis Workbook for Community/Ambulatory Pharmacy*. The workbook is designed to assist community pharmacy personnel in completing RCA for a sentinel event that may have occurred in their pharmacy. The RCA workbook uses a specific set of steps and associated tools to identify the primary causes of the **sentinel event**.

The goal of the RCA is to create an action plan framework, including risk-reduction strategies, communication and implementation strategies, and measurement of effectiveness.

RCA for **sentinel events** is required in the Center for Pharmacy Practice Accreditation’s standards developed by NABP, American Pharmacists Association, and American Society of Health-System Pharmacists Association, as well as by several boards of pharmacy in conjunction with their continuous quality improvement regulations.

This ISMP RCA workbook is suitable for use in community pharmacy, mail-order pharmacy, or other ambulatory pharmacy practice settings that need to investigate a **sentinel event**. For more information and to access the **free** workbook, visit [www.ismp.org/tools/rca/](http://www.ismp.org/tools/rca/).

<sup>1</sup><http://pediatrics.aappublications.org/content/113/2/406.abstract>



## **FDA Withdraws Approval of Some High Dose Acetaminophen Products**

Food and Drug Administration (FDA) is withdrawing approval of 108 abbreviated new drug applications (ANDAs) for prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit. For the 108 ANDAs, the manufacturers asked to withdraw their applications, as announced in the March 27, 2014 *Federal Register* notice. A second *Federal Register* notice addresses the applications of six manufacturers who have discontinued marketing their products, but who have not withdrawn their applications. The notice also announces FDA's intention to begin the process of withdrawing approval of those applications.

In light of these announcements, and to protect patients from inadvertent acetaminophen overdose, NABP advises that pharmacies no longer dispense combination drugs containing more than 325 mg of acetaminophen per dosage unit. NABP also advises that pharmacists consult with prescribers to discuss alternative products with lower acetaminophen doses.

FDA asked manufacturers to voluntarily withdraw these products from the market to reduce the risk of severe liver injury from inadvertent acetaminophen overdose. In January 2014, FDA recommended that providers consider prescribing acetaminophen products containing 325 mg or less per dose. The original announcement may be found in the Drug Safety and Availability section of FDA's website at [www.fda.gov/Drugs/DrugSafety](http://www.fda.gov/Drugs/DrugSafety).

## **NCPDP Recommends Standardized Metric Measurements on Oral Liquid Medication Labels**

The National Council for Prescription Drug Programs (NCPDP) has issued new recommendations and guidance for standardizing the dosing designation used on prescription container labels of oral liquid medications dispensed by community pharmacies in order to reduce dosing errors. NCPDP notes that such errors have been "a source of concern for many years," and that dosing errors involving young children are of particular concern because they may be more susceptible to harm from measurement errors and overdoses. The paper outlines the following recommendations for the dosing designation on prescription container labels for oral liquid medications:

- ◆ The millimeter (mL) should be used as a standard unit of measurement.
- ◆ Dose amounts should always use leading zeros before decimal points for amounts less than one and should not use trailing zeros after a decimal point.

- ◆ Dosing devices with numeric graduations and units corresponding to the container label should be made easily and universally available. For example, a device should be included with each dispensed medication.

The white paper was developed following a meeting with stakeholders representing 27 participants, including NABP. In addition to its general recommendations, the white paper also issued calls to action for relevant stakeholders, including government agencies, standards organizations, pharmacists and pharmacy technicians, pharmacy leadership, and health care associations. The white paper, *NCPDP Recommendations and Guidance for Standardizing the Dosing Designations on Prescription Container Labels of Oral Liquid Medications*, is available for download from the NCPDP website at <http://ncdp.org/Education/Whitepaper>.

## **USP Proposes New General Chapter Addressing Compounding of Hazardous Drugs**

In an effort to protect health care providers and personnel who handle hazardous drugs, United States Pharmacopeial Convention (USP) has proposed new General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings. The new proposed chapter addresses standards that apply to all personnel who compound hazardous drug preparations and all places where hazardous drugs are prepared, stored, transported, and administered. The new chapter also covers standards for receiving, storing, compounding, dispensing, administering, and disposing of nonsterile and sterile products and preparations. The proposed chapter applies to all personnel who are involved in handling hazardous drugs, including health care providers and staff, occupational health and safety specialists, and human resources. General Chapter <800> was published in the May/June issue of *Pharmacopeial Forum*, and may currently be viewed on the USP website at [www.usp.org/usp-nf](http://www.usp.org/usp-nf). Comments were accepted until July 31, 2014.



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Continuing pharmacy education (CPE) providers who are accredited by the Accreditation Council for Pharmacy Education (ACPE) have integrated CPE Monitor® into their systems and are requiring pharmacists and pharmacy technicians to provide an NABP e-Profile ID number and date of birth (MMDD) in order to process ACPE-accredited CPE credit.

Visit [www.MyCPEmonitor.net](http://www.MyCPEmonitor.net) to set up your NABP e-Profile and register for CPE Monitor and avoid possible delays in your CPE reporting.

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that “a pharmacist who administers any vaccine will follow storage and handling guidance from the vaccine manufacturer and the Centers for Disease Control and Prevention.” Be sure to manage your temperature logs appropriately and recognize that the intention of this monitoring is to ensure that your drug supply has been stored properly and that vaccines are effective and safe to administer. At a minimum, a pharmacy is expected to log the temperatures at least once per day. Additionally, a pharmacy is expected to have current policies and procedures for staff to follow in the event that the temperature falls out of range. What will you do if you realize that power to your pharmacy’s refrigerator was disrupted overnight, potentially negatively affecting your vaccines? What happens if your refrigerator records a freezing temperature? May the vaccine(s) still be administered?

- ◆ **Remember to Utilize the ALERT IIS:** This handy database is useful to provide quality care to your patients. Because all immunization data are uploaded to the system regularly by pharmacists and other immunizing health care professionals, it can be a source of information for your professional drug utilization review processes. Recall that step one of each protocol states, “Check the ALERT IIS to determine whether the patient needs this vaccine and any other vaccines.” Take a moment to confirm that your immunizing pharmacists and interns have access to the system, understand the intention of the forecasting responsibility, and are fulfilling that responsibility. Did you know that technicians can register to be users of the database as well? The Oregon Immunization Program (OIP) allows for “providers” agents working under the guidance of a practitioner to assist with the database lookups. Additionally, by the end of the year, the OIP plans to incorporate the ability for the user to reset his or her password directly from the ALERT Immunization Information System (IIS) website. For questions, please contact the ALERT IIS help desk at 800/980-9431 or via e-mail at [alertiis@state.or.us](mailto:alertiis@state.or.us).

Pharmacists across the state play a key role in prevention and wellness in our communities. The Oregon Health

Authority’s OIP analyzed data submitted to the ALERT IIS and published a report about rates of influenza vaccinations in Oregon during the 2013-2014 influenza season and determined the following conclusions:

- ◆ Seasonal flu immunizations began in September, peaked in mid-October, and steadily declined into the holiday season. A second spike occurred around mid-January, likely due to news media coverage of influenza and the presence of cases in local communities.
- ◆ Young children and older adults have the highest flu immunization rates, while young adults remain the least vaccinated member of society. It is important for pharmacists and interns to identify these individuals in the pharmacy and initiate conversations with them regarding the merits of flu vaccination. Many people may not be worried for their own health and the risks associated with the flu; however, their capacity to spread the disease to more vulnerable populations is a public health concern. For example, young adults tend to work in positions with close public contact, such as cashiering or working in other service industries, and can more easily spread disease.
- ◆ Patterns of immunization rates across the state suggest that pharmacists are filling an unmet need for influenza immunizations in our communities, especially where barriers to adult vaccinations exist in the traditional medical model.

The complete 2013-2014 flu vaccination report, authored by Steve Robison, an OIP epidemiologist, can be read in its entirety on the Board’s website at [www.oregon.gov/pharmacy/Imports/2013-14\\_OregonInfluenzaReport.pdf](http://www.oregon.gov/pharmacy/Imports/2013-14_OregonInfluenzaReport.pdf).

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