



Oregon State Board of Pharmacy

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No. 581 Board Member News

The Oregon State Board of Pharmacy wishes to thank Pharmacist Ken Wells for his commitment to serving the citizens of Oregon. Ken brought a wealth of leadership, pharmacist knowledge, a strong community pharmacy background, as well as pharmacy management and regular awareness of patient safety to the Board's conversations during his eight years of service. Influenza H1N1 hit just as he joined the Board in 2009, and the Board had to move quickly to respond with an update to the Board's public health emergency rules. Over the years, Ken has been instrumental in conversations related to patient safety, particularly helping craft solutions and gaining stakeholder input for the development of the groundbreaking workplace environment rules. More recently, Ken facilitated discussions and policy-making related to such issues as medication error prevention, Technician Checking Validation Program procedures, central fill, remote processing and drugless pharmacies, auto refills, non-pharmacy dispensing, and pharmacist autonomous prescribing of contraceptives and naloxone, to name a few. Additionally, Ken is a highly regarded speaker, and he presented at multiple outreach efforts on behalf of the Board at various Oregon State Pharmacy Association meetings. Ken, thank you for your leadership and all you have given to the community over the years – the Board is so very appreciative.

No. 582 Drug Disposal – Collection Receptacles and Take-Back Initiatives

By Kayllie LaPointe, 2017 PharmD Candidate, Pacific University

In February 2017, the Board adopted rules related to pharmacy-affiliated secure and responsible drug disposal sites. To summarize, these rules allow drug disposal collection receptacles in pharmacy waiting areas that can be used by the general public for the disposal of unwanted medications. A person may discard prescription drugs as well as unwanted over-the-counter medications. Drug Enforcement Administration (DEA) created regulations that provide patients with a method to dispose of these items. Because of the high rate

of opioid dependence and overdose deaths, it is hopeful that this initiative will reduce the amount of prescription opioids in our communities and thereby have a positive impact on society. More information can be found on DEA's drug take-back web page at https://www.deadiversion.usdoj.gov/drug_disposal/index.html.

New programs are often accompanied by the importance of understanding the new rules for pharmacy collection of unused medications and safe drug disposal. These rules align with DEA regulations associated with the Secure and Responsible Drug Disposal Act of 2010 (see Title 21 Code of Federal Regulations (CFR) §1317 – Disposal at <https://www.deadiversion.usdoj.gov/21cfr/cfr/2117cfrt.htm>). The overall goal is to allow ultimate users (patients) to deliver unused pharmaceutical controlled and non-controlled substances to appropriate entities for disposal in a safe and effective manner, consistent with effective controls against diversion. To comply, an interested pharmacy must modify its DEA registration to become an authorized collector and then follow the rules to install a collection receptacle for the public to use.

The Board's Administrative Rules can be found in Division 041 (see [Oregon Administrative Rule \(OAR\) 855-041-1046](#)). Some highlights of the laws and rules include:

- ◆ The pharmacy is to notify the Board of plans to be a collection site.
- ◆ The pharmacy must follow all DEA regulations set forth in 21 CFR §1317.
- ◆ The collection receptacle **cannot** be located behind the pharmacy counter!
- ◆ Staff should plan to remove the inner liner when the hauler arrives to pick it up.
- ◆ Pharmacy staff **cannot** handle drugs collected.
- ◆ The pharmacy **cannot** dispose of unwanted inventory in the receptacle.
- ◆ The pharmacy can host a take-back event off site, but must work in collaboration with local law enforcement.

It is important to note that participation is voluntary but encouraged, as it is the right thing to do for our local communities.

WHO Launches Global Patient Safety Challenge on Medication Safety

To reduce severe, avoidable medication-associated harm in all countries by 50% over the next five years, the World Health Organization (WHO) has launched a worldwide initiative, the Global Patient Safety Challenge on Medication Safety. Medication errors cause at least one death every day and injure approximately 1.3 million people every year in the United States. In addition, low- and middle-income countries are estimated to have similar rates of medication-related adverse events as high-income countries.

The Global Patient Safety Challenge on Medication Safety aims to make improvements in each stage of the medication use process including prescribing, dispensing, administering, monitoring, and use. WHO intends to provide guidance and develop strategies, in addition to plans and tools to ensure that the medication process has the safety of patients at its core in all health care facilities.

Previous WHO Global Safety Challenges have included the Clean Care is Safer Care challenge on hand hygiene in 2005 and the Safe Surgery Saves Lives challenge in 2008. Additional information is available in the WHO press release available at <http://who.int/mediacentre/news/releases/2017/medication-related-errors/en>.

Continuous Quality Improvement and Patient Safety Organizations

 *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.*

Data from the ISMP Medication Errors Reporting Program reveals that medication-related problems are repetitive in nature. An incident of misuse in one setting is likely to repeat itself in another. Most importantly, the system changes that are necessary to prevent errors are similar, and a growing body of literature is available to guide these efforts. Tragically, too many organizations and individual providers do not believe similar incidents could happen to them. They fail to use information about errors occurring elsewhere as a roadmap for improvement in their own organization or practice. It is not until a serious error hits home that aggressive prevention efforts are implemented. With so much evidence-based information about error prevention at hand, there is little excuse for reacting to errors after they happen instead of preventing them.

The development and implementation of continuous quality improvement (CQI) efforts should be the highest priority in all pharmacies. Such efforts must be aimed specifically at preventing

well-known and repetitive dispensing errors. Pharmacies should seek out medication safety information and use it proactively to prevent medication errors. At the same time, safety issues recognized internally and/or reported by patients should be documented and analyzed, with a process to determine the best strategies to prevent future problems and methods to ensure implementation. An annual survey to assess consumer perceptions of the quality of pharmaceutical products and professional services could supply additional information upon which to base improvement strategies. For more information on CQI programs, visit Section 7 of Model Rules for the Practice of Pharmacy in *The Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*.

Informational tools like the *ISMP Medication Safety Alert!* publication, or ISMP's *Quarterly Action Agenda*, which is a readily available list of medication problems compiled from the nation's reporting programs, can be a backbone of any CQI effort. The very purpose of the ISMP Medication Errors Reporting Program – indeed the purpose of any type of safety reporting program and the expert recommendations that stem from it – is to guide the implementation of quality improvement initiatives by practitioners and organizations.

It is important that certain information from the CQI proceedings and records of review be protected from discovery. Patient safety organizations (PSO) are organizations that share the goal of improving the quality and safety of health care delivery. Patient Safety Work Product (PSWP) is the information protected by the privilege and confidentiality protections of the Patient Safety Act and Patient Safety Rule. PSOs serve as independent, external experts who can collect, analyze, and aggregate PSWP locally, regionally, and nationally to develop insights into the underlying causes of patient safety events, thus improving quality by identifying and reducing the risks and hazards associated with patient care. Communications with PSOs are protected to allay fears of increased risk of liability because of collection and analysis of patient safety events.

For more information on PSOs, visit <https://www.pso.ahrq.gov/faq>.

NCPDP Releases Guide to Ensure Patients Get Their Medications During a Disaster

The National Council for Prescription Drug Programs (NCPDP) released the *NCPDP Emergency Preparedness Information* guide to assist pharmacists and other health care providers during a declared emergency. Prepared by the NCPDP Emergency Preparedness Committee, the guide provides resource information for eligibility and claims processing affecting displaced individuals. The guide is available at www.ncdp.org/NCPDP/media/pdf/NCPDPEmergencyPreparednessInformation_v1_4.pdf. Additional information for pharmacists about emergency preparedness is available on the NCPDP website at www.ncdp.org/Resources/Emergency-Preparedness.

FDA Warns of Illnesses and Deaths in Pets Exposed to Fluorouracil

Food and Drug Administration (FDA) is alerting pharmacists that patients' pets are at risk of illness and death when exposed to the topical cancer medication fluorouracil cream USP 5% (5-FU) that is intended for use in people. Fluorouracil may also be marketed under the brand names Carac®, Efundex®, and

News to a particular state or jurisdiction can only be ascertained
such state or jurisdiction.

Fluoroplex®. Very small amounts could be dangerous to household pets; thus, patients should use care when applying and storing the medication. FDA has received reports of five dogs that became ill and died after accidentally ingesting the topical cream, notes a Center for Veterinary Medicine Update available at www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm537434.htm.

Although FDA has not received any reports involving cats to date, cats are also expected to be extremely sensitive to fluorouracil cream. For instance, if an owner applies fluorouracil cream to an afflicted area and touches his or her cat, the cat may accidentally ingest the medication when grooming itself and suffer adverse events.

FDA advises that pharmacists who fill these prescriptions should advise patients with pets to prevent exposing their pet to the medication. Adverse events may be reported to FDA using the Form FDA 1932a, which may be obtained at www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm055305.htm.

FDA Revises Final Guidance Documents on Bulk Drug Substances Used in Compounding

In January 2017, FDA issued revised versions of two final guidance documents regarding the use of bulk drug substances in compounding.

- ◆ Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act
- ◆ Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act

FDA clarified that the policies described in the guidances do not apply to inactive ingredients. Inactive ingredients are not included in the definition of a “bulk drug substance” and can be used in compounding without appearing on the bulk drug substances lists developed under sections 503A or 503B of the Federal Food, Drug, and Cosmetic Act, if all applicable conditions are met.

As indicated on its website at www.fda.gov/Drugs/DrugSafety/ucm502075.htm, FDA will also provide regular updates to the categories of bulk drug substances described in the guidances. FDA previously stated that it would not evaluate new nominations for placement in one of the three categories until after it completed its review of substances already nominated with adequate supporting information.

Now, the guidances state that FDA will determine after submissions are received whether new nominations, including renominations of substances with additional supporting information, have sufficient information for FDA to review them. After making that determination, FDA will place nominated substances in the appropriate category on FDA’s website. FDA intends to update the categories with any new nominations the first business day of each month. This revised policy will further minimize unnecessary disruptions to patient treatment while FDA develops the lists of bulk drug substances for use in compounding.

The guidances are available online at www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469120.pdf and www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469122.pdf.

APhA Resource Guide Applies JCPP Pharmacists’ Patient Care Process to Immunization Services

The American Pharmacists Association (APhA) published a resource guide that applies the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacists’ Patient Care Process to pharmacy-based immunization services. The components of the Pharmacists’ Patient Care Process to collect, assess, plan, implement, and follow-up should be implemented as routine practice along with the National Vaccine Advisory Committee Standards for Adult Immunization Practice, as noted in the resource guide, *Applying the Pharmacists’ Patient Care Process to Immunization Services*. “[P]harmacists and other vaccine providers need to strive to constantly improve collaboration, communication, and documentation,” indicates the APhA guide. For more information, visit the APhA Immunization Center at www.pharmacist.com/immunization-center.

CPE Training on Older Adult Fall Prevention Available Online

Developed in collaboration with the Centers for Disease Control and Prevention (CDC) and the APhA, the Stopping Elderly Accidents, Deaths, and Injuries (STEADI) initiative is offering continuing pharmacy education (CPE) training for pharmacists to prevent falls in adults 65 and older. The training will provide strategies to help pharmacists screen older adults for fall risk, conduct medication review and management, and offer patient education. To participate in the free online training, “STEADI: The Pharmacist’s Role in Older Adult Fall Prevention,” visit the CDC website at www.cdc.gov/steadi/training.html for more information.

New FDA Drug Info Rounds Training Video Addresses the Combat Methamphetamine Epidemic Act

Drug Info Rounds, a series of online videos by FDA, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the latest Drug Info Rounds video, “Combat Methamphetamine Epidemic Act,” pharmacists discuss the legal requirements for the sale of over-the-counter drug products that contain pseudoephedrine. Drug Info Rounds was 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.

FDA Presents Series of CE Webinars for Students and Clinicians

FDA’s Division of Drug Information in the CDER presents a series of continuing education (CE) 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. Previous webinar topics have included an overview of FDA’s role in medication error prevention and prescription drug labeling. The webinars and presentation slides can be accessed on FDA’s website at www.fda.gov/DDIWebinars.

No. 583: The Oregon Prescription Drug Program

The Oregon Prescription Drug Program (OPDP) is a resource for patients who may have difficulty affording their medications. All Oregon residents who are underinsured can enroll in OPDP to obtain a free prescription discount card. This state-sponsored program allows enrollees to save up to 80% off of their generic prescriptions. All Food and Drug Administration-approved drugs prescribed by a licensed clinician are eligible for the discount. There are no age or income restrictions. Enrollees can also use the discount card if they have other prescription coverage – for instance, when insurance does not cover a particular prescription or when pricing with the OPDP discount card is better than the insurance. OPDP is part of the larger Northwest Prescription Drug Consortium, which provides greater leverage for negotiating lower prices. Costs for medications at participating pharmacies can be looked up on the OPDP website. A person can enroll by calling 1-800/913-4284 or visiting the website at www.opdp.org.

No. 584 New Oregon Dextromethorphan Regulations – Age Restrictions

In June 2017, Governor Kate Brown signed Senate Bill (SB) 743, which prohibits the nonprescription sale of dextromethorphan to individuals younger than 18 years of age. The bill goes into effect on January 1, 2018. SB 743 prohibits the sale or delivery of any dextromethorphan-containing product to an individual younger than 18 years of age unless he or she has a valid prescription.

This bill will be enforced by law enforcement agencies in similar fashion to the current processes for tobacco and alcohol sales. The bill only imposes a requirement that a retailer manually obtain and verify proof of age as a condition of the sale of a dextromethorphan-containing product.

The Board anticipates that this will impact pharmacies in two ways. The first will require the implementation of internal processes for checking the age of anyone purchasing dextromethorphan, and the second will be a possible increase in dextromethorphan prescriptions for individuals under the age of 18. Rather than wait until the last minute, the Board recommends that you start creating a strategy now to be compliant with the new statute, as the Board expects law enforcement will begin to enforce this law sometime in January 2018. To view the bill, visit <https://olis.leg.state.or.us/liz/2017R1/Downloads/MeasureDocument/SB743/Enrolled>.

No. 585 Wholesaler Reporting Requirement

Effective July 2017, a wholesale distributor that distributes in or into Oregon must notify the Board of suspicious orders of controlled substances upon discovery. A suspicious order may include an order of unusual size, an order deviating substantially from a normal pattern, and orders of unusual frequency. Title 21 CFR §1301.74 requires DEA registrants to disclose these suspicious orders to DEA, and this new rule requires the same notification be provided to the Board (see OAR 855-065-0010).

No. 586 Due Diligence for Validation of Pharmacy Employees

In an effort to maintain security, it is critical for all pharmacy staff members to remain vigilant about who they allow to enter the pharmacy at any time. The Board stresses the utilization of professional judgment and due diligence of the pharmacist-in-charge as well as all staff pharmacists when making security and safety determinations. For example, before a new pharmacist or technician employee enters a pharmacy, pharmacy staff shall be sure the person holds an active license with the Board. Validation of active licensure can be achieved by following this straightforward process: simply link to the Online License Lookup & Verifications site on the Board's home page (<https://obop.oregon.gov/LicenseLookup>) and enter the person's name. Additionally, this is a great tool for interns to utilize when confirming that practical experiences will be overseen by active preceptors. This active assessment of a person's license status prior to inviting him or her into your pharmacy truly exemplifies the Board's longstanding intent for posting licenses on its website. While it seems simple, the single most important component that fundamentally allows a pharmacist to practice pharmacy and a technician to assist is an active license.

Further, no pharmacy employee shall perform duties in a pharmacy unless he or she is appropriately trained. Training must be documented, and records shall be readily retrievable. Be sure to know a new pharmacy employee's documented training and proficiencies before allowing him or her to work in your pharmacy. These validation processes are the responsibility of all pharmacy staff members and pharmacy outlets.

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