May 2017

Oregon State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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No. 576: Board Newsletter Goes Solely Electronic

Beginning July 1, 2017, the National Association of Boards of Pharmacy Foundation® will no longer be offering the print option for its State Newsletter Program. This is the last issue of the Oregon State Board of Pharmacy's printed *Newsletter.* Going forward, all future Board *Newsletters* will be provided as a downloadable PDF posted on the National Association of Boards of Pharmacy® (NABP®) website, which can be accessed directly or through the Board's link at *http://www.oregon.gov/pharmacy/pages/newsletters.aspx.* Licensees can sign up for a free email alert to receive a reminder whenever a new issue of the *Newsletter* becomes available. To sign up for the email alert, visit the Board's contact page in the Boards of Pharmacy section of the NABP website at *www.nabp.pharmacy* and click the subscribe link. The Board is undertaking this effort to deliver updates as timely as possible and make the information more easily accessible.

Per Oregon Administrative Rule (OAR) 855-041-1035(2), retail and institutional drug outlets must maintain a minimum of three years of the Board's quarterly *Newsletter,* in house or by other readily retrievable means. Please take the time to ensure your pharmacy provides access to the quarterly *Newsletter* and that licensees have direct access to this important publication.

No. 577: Oregon Board Member and Staff News

The Board wants to wish a fond farewell to Public Member Heather Anderson, who completed her four-year term in February 2017. Heather brought a unique voice to the Board's conversations during her years of service. Her engineering and technology backgrounds encouraged the Board to consider issues in an alternative manner. Heather was instrumental in her participation on the Auto Refill Workgroup and arranged for an appearance related to certain aspects of licensing anti-trust and anti-consumer issues. Heather attended nearly every rulemaking hearing and could always be counted on to be a strong advocate for outlet and individual accountability, with patient safety at the forefront. Thank you for your years of service, Heather!

Brianne Efremoff accepted the compliance director position for the Board, effective November 2016. Brianne is a 2009 graduate of the University of the Sciences Philadelphia College of Pharmacy and hails from the east, but feels privileged to call Oregon her home. She joined the Board compliance team in February 2014 as a pharmacy investigator. During her time as an investigator, she participated in a wide variety of activities, including inspections, investigations, educational outreach to both licensees and the pubic, rule writing, and writing questions for the Multistate Pharmacy Jurisprudence Examination®. She has a strong passion for patient care and approaches difficult situations with enthusiasm. Brianne seeks knowledge and looks forward to the challenges that her new position as compliance director will bring. She credits her ability to take on this new role to the amazing team at the Board office and the vast knowledge, patience, and leadership exhibited by her predecessor, Gary Miner.

In March 2017, the Board hired two pharmacy inspectors to complete the compliance team. The Board welcomes Jane Gin and Brian Murch. Jane is an Oregon native and attended Oregon State University College of Pharmacy (Go Beavs!). She has worked in a variety of community pharmacy settings in Idaho and Oregon for the past five years and is excited to delve into another aspect of pharmacy as a part of the Board team. Jane loves visiting the Oregon coast, drinking copious amounts of coffee, spending leisure time with her dogs, and discovering Portland, OR's extensive food scene.

Brian worked in retail pharmacy for the last 12 years. He is truly excited to join the Board and the fast-paced world of compliance. He is originally from the booming metropolis of Odessa, NY, and attended pharmacy school at State University of New York at Buffalo. Brian migrated to Oregon in 2012. When not at work, he spends most of his time with his wife, Kate, and their seven-month-old daughter "Peanut" (Maggie). He has two dogs, Charlie the Dog and Sir Walter McRuffington III. He loves food, travel, his giant family, *Law and Order* reruns, Syracuse Orange basketball, the Seattle Mariners, and a good pair of sweatpants.

The Board has a full compliance staff once again.

No. 578: Saving Trees and Changes to Rulemaking and Agenda Communications

In an effort to be environmentally responsive and save your licensing dollars, the Board is moving toward a more streamlined and paperless environment. The Board expects to save over $10,000 annually in printing and mailing costs, save some trees, and save you time from tossing mail you are not interested

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DEA Changes Registration Renewal Process

As of January 2017, Drug Enforcement Administration (DEA) will no longer send its second renewal notification by mail. Instead, an electronic reminder to renew will be sent to the email address associated with the DEA registration.

In addition, DEA will retain its current policy and procedures with respect to renewal and reinstatement of registration. The policy is described below.

- If a renewal application is submitted in a timely manner prior to expiration, the registrant may continue operations, authorized by the registration, beyond the expiration date until final action is taken on the application.
- DEA allows the reinstatement of an expired registration for one calendar month after the expiration date. If the registration is not renewed within that calendar month, an application for a new DEA registration will be required.
- Regardless of whether a registration is reinstated within the calendar month after expiration, federal law prohibits the handling of controlled substances or List 1 chemicals for any period of time under an expired registration.

Additional information is available on the DEA website at *www.deadiversion.usdoj.gov/drugreg/index.html.*

ISMP Medication Safety Self Assessment for Community/Ambulatory Pharmacy

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.*

Pharmacists in community and ambulatory settings can now access a newly revised tool that will help them review and improve their medication safety practices. The 2017 Institute for Safe Medication Practices (ISMP) Medication Safety Self Assessment® for Community/Ambulatory Pharmacy is designed to help pharmacies evaluate their current systems, proactively identify opportunities for improvement, and track their efforts over time.

An advisory panel of experts helped ISMP update items from the 2001 community/ambulatory self-assessment as well as add items to address new practices and processes, including the pharmacist's evolving role in immunization administration. New research findings about error prevention and emerging technologies previously not widely adopted are also covered.

The self-assessment contains items that address the use of medications in the clinical setting, many of which are on the ISMP list of high-alert medications. Many of the items included represent system improvements and safeguards that ISMP has recommended in response to analysis of medication errors reported to the ISMP Medication Errors Reporting Program, problems identified during on-site consultations with health care organizations, and guidelines in medical literature.

The self-assessment is divided into 10 key elements that most significantly influence safe medication use. Each element is defined by one or more core characteristics of a safe pharmacy system that further define a safe medication use system. Each core characteristic contains individual self-assessment items to help evaluate success with achieving each core characteristic.

ISMP recommends that each pharmacy site convene its own team of staff members (ie, pharmacist(s), technician(s), and student pharmacist(s)) to complete this comprehensive assessment and use the information as part of its ongoing safety and quality improvement efforts. An online form has been provided to help participants organize and score their responses. **Important:** The self-assessment should be completed in its entirety by staff and managers who work within the pharmacy, not by off-site managers on behalf of the pharmacy.

When the self-assessment is completed, respondents can generate reports showing how their pharmacy answered each item and how they scored on each as a percentage of the maximum possible score. The pharmacy can then use its scores to identify and prioritize opportunities for its safety plan of action.

ISMP is not a regulatory or standards-setting organization. As such, the self-assessment characteristics represent ideal practices and are not purported to represent a minimum standard of practice. Some of the self-assessment criteria represent innovative practices and system enhancements that are not widely available in pharmacies today. However, the value of these practices in reducing errors is grounded in expert analysis of medication errors, scientific research, or strong evidence of their ability to reduce errors.

To view, download, and print the PDF of the assessment, which includes the introduction, instructions for use, self-assessment items, and definitions, visit *https://www.ismp.org/Survey/NewMssacap/Index.asp.*

CDC Publishes Resource to Foster Use of JCPP Pharmacists' Patient Care Process

A publication intended to encourage the use of the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacists' Patient Care Process was released by the Centers for Disease Control and Prevention's (CDC's) Division for Heart Disease and Stroke Prevention. In *Using the Pharmacists' Patient Care Process to Manage High Blood Pressure: A Resource Guide for Pharmacists,* CDC calls on pharmacists and other health care providers to implement the Pharmacists' Patient Care Process model to reduce heart disease and stroke in the United States. Pharmacists can have a positive effect on population health by providing patient care services and participating in collaborative practice agreements and continuing education (CE) programs, notes the CDC publication. The publication is available at *www.cdc.gov/dhdsp/pubs/docs/pharmacist-resource-guide.pdf.*

The National Association of Boards of Pharmacy® (NABP®) is a member of JCPP and endorses the Pharmacists' Patient Care Process. In its September 2015 newsletter (page 167), NABP discusses integrating the JCPP Pharmacists' Patient Care Process to improve medication outcomes and promote consistency in patient care service delivery. Additional information about JCPP is available at *https://jcpp.net.*

FDA Issues Final Guidance on Repackaging Drugs by Pharmacies and Registered Outsourcing Facilities

In January 2017, Food and Drug Administration (FDA) issued a final guidance for industry titled, "Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities." This guidance describes the conditions under which FDA does not intend to take action for violations of certain provisions of the Federal Food, Drug, and Cosmetic Act when a state-licensed pharmacy, a federal facility, or an outsourcing facility repackages certain human drug products. The guidance is available at *www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM434174.pdf.*

Electronic or written comments may be submitted at any time for this final guidance following the instructions provided in the *Federal Register,* which can be found at *www.federalregister.gov/documents/2017/01/13/2017-00723/repackaging-of-certain-human-drug-products-by-pharmacies-and-outsourcing-facilities-final-guidance.*

CriticalPoint Launches QP503A Certification Program for Sterile Compounding in 2017

In 2017, CriticalPoint, LLC, launched its QP503A certification program for sterile compounding personnel. Specifically, CriticalPoint is offering the QP503A Certification and the QP503A Master Certification, which may be earned after obtaining the basic QP503A Certification. Participants will gain vital knowledge and skills to successfully plan, develop, and operate a 503A pharmacy sterile compounding operation.

The QP503A Certification involves a didactic program of home study, live training, and practicum activities accompanied by required objective personnel and cognitive testing. The QP503A Master Certification requires participants to demonstrate their ability to apply their QP503A Certification training in actual work settings and produce measurable changes in sterile compounding processes resulting in improved patient safety.

Additional details about these programs and the certification requirements are available online at *www.criticalpoint.info/wp-content/uploads/CriticalPoint-QP503A-Certification.pdf.*

PTCB Suspends Implementation of Planned 2020 Accredited Education Requirement for Pharmacy Technicians

The Pharmacy Technician Certification Board (PTCB) is suspending the implementation of the accredited education requirement for pharmacy technicians. In 2013, PTCB announced that the requirement would take effect in 2020, but PTCB has "determined that additional deliberation and research are needed to address stakeholder input, develop supporting policy, and conduct further study of technician roles," said Larry Wagenknecht, BPharm, chair of the PTCB Board of Governors, and chief executive officer of the Michigan Pharmacists Association, in a news release. The role of pharmacy technicians is evolving, and PTCB is taking steps to support the pharmacy community.

PTCB recently completed a job analysis study to collect data on current roles and responsibilities of pharmacy technicians across all practice settings to update PTCB's Pharmacy Technician Certification Exam and is in the process of developing advanced certification programs. In addition, PTCB hosted an invitational conference in February 2017 where pharmacy leaders and stakeholders examined entry-level standards and provided information to help determine future plans for implementing PTCB program changes.

PTCB's news release is available at *www.ptcb.org* in the News Room section.

ASOP Global Spreads Awareness About Illegal Online Drug Sellers and Counterfeit Medications

Alliance for Safe Online Pharmacies (ASOP Global) partnered with several nonprofit organizations, including NABP, to launch a campaign to raise awareness of illegal online drug sellers and counterfeit medications. The campaign encourages dialogue among health care providers and patients regarding where patients purchase their medications, especially if patients are buying them online.

After offering the CE course "Internet Drug Sellers: What Providers Need to Know" to over 1,000 health care providers, ASOP Global found that less than 10% of providers reported they were "very aware" counterfeit prescription drugs are being sold on the internet and only 1.4% said they regularly discuss the risks of illegal internet drug sellers with patients. ASOP Global Executive Director Libby Baney said, "After completing the course, however, there was a ten-fold increase in the expected frequency in which providers planned to discuss the risks associated with buying prescription medicines online with their patients and what they can do to avoid physical and financial harm."

For more information about the campaign, visit *www.BuySafeRx.pharmacy.*

New Interactive Map Tracks Pharmacist Vaccination Laws

A new resource – an interactive 50-state map tracking pharmacist vaccination laws between 1990 and 2016 – was published by The Policy Surveillance Program, A LawAtlas Project. The map, which is available at *http://lawatlas.org/datasets/pharmacist-vaccination,* explores laws that give pharmacists authority to administer vaccines and establish requirements for third-party vaccination authorization, patient age restrictions, and specific vaccination practice requirements, such as training, reporting, record keeping, notification, malpractice insurance, and emergency exceptions. The Policy Surveillance Program is administered by Temple University Beasley School of Law.

National Association of Boards of Pharmacy Foundation
1600 Feehanville Drive
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in or decluttering your email inbox from things that you really do not want. The Board is changing to a more manageable, free, subscription-driven email distribution to provide information about rulemaking activities and the Board's meeting agenda. If interested, please subscribe to either or both of the lists, which can be found on the Board's home page under **"Sign up to receive Agenda, Rules & Newsletters."**

- For rulemaking, effective July 31, 2017, the Board will no longer be printing/mailing postcards to all licensees or outlets who are potentially affected or sending potentially duplicate email to all pharmacists, interns, pharmacy technicians, corporate outlets, or rules interested parties.
- For agenda interested parties, this will be the new method of communication for agenda and mailings.

The Board will continue to post all notices of rulemaking activities on the Board website's home page when there is something coming up, under "What's Hot," as well as on the Laws & Rules page at *http://www.oregon.gov/pharmacy/Pages/Laws_Rules.aspx.* The Board meeting agenda will also continue to be posted on the Board's home page prior to each Board meeting under "Topics of Interest" as well as on the "Board Meetings" page.

These changes create efficiencies all around for Board staff and hopefully for you too. If you subscribe and decide you do not want this information in the future, you will have the opportunity to unsubscribe.

If you wish to continue receiving information about rulemaking actions, please visit *www.pharmacy.state.or.us* and subscribe to an automated email list for rules or the Board meeting agenda.

If you wish to continue to receive rulemaking information by United States mail, please send a written request to receive rulemaking information to Oregon State Board of Pharmacy, Attn: Rules, 800 NE Oregon St, Suite 150, Portland, OR 97232, or email your name and mailing address to pharmacy.board@state.or.us with "Rulemaking Notice" in the subject line.

No. 579: Pharmacist-in-Charge Change Form

By Tim Ma, 2017 PharmD Candidate

Oregon is now offering a new way to submit pharmacist-in-charge (PIC) change forms. Oregon is one of the few states to offer an online submission form for incoming and outgoing change of PICs. The online form went live in early March 2017. Previously, these forms were filled out and then mailed, emailed, or faxed. The Board is no longer accepting emailed, mailed, or faxed forms. Reporting of a PIC change must be done via online submission. Both the incoming and outgoing PIC must fill out their corresponding forms on the Board website under the Forms tab. The required fields must be filled in when submitting the form.

As a reminder, there are some important duties to complete when there is a change in PIC, per OAR 855-019-0300:

- Complete a Board-approved PIC training course either before the appointment or within 30 days after appointment, **if** you have practiced less than a year as a pharmacist.
- When a change of PIC occurs, both outgoing and incoming PICs must report the change to the Board within 15 days of occurrence on a form provided by the Board.
- The new PIC must complete an inspection on the PIC Annual Self-Inspection Form within 15 days of becoming PIC.
- An inventory of all controlled substances must be taken within 15 days before or after the effective date of change of PIC and must be dated and signed by the new PIC. This inventory must be maintained in the pharmacy for three years and in accordance with all federal laws and regulations.

No. 580: New Outlet Reporting Requirement

Effective February 23, 2017, a resident pharmacy outlet that terminates or allows a Board licensee to resign in lieu of termination must report the termination or resignation to the Board within 10 working days. The report can be made directly to the Board office, via written letter or email. The notification shall include the name of the pharmacist or technician who was terminated or who was allowed to resign in lieu termination, as well as the name of the individual making the report. Please include if the termination was due to a suspected violation.

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.

Marc Watt, RPh - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
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