April 2017

News

Washington State Pharmacy Quality Assurance Commission

Published to promote compliance of pharmacy and drug law

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www.doh.wa.gov/LicensesPermitsandCertificates/ProfessionsNewReneworUpdate/PharmacyCommission.aspx

No. 1251 Pharmacy Technology Rules

The Washington State Pharmacy Quality Assurance Commission adopted proposed language regarding the use of automated drug dispensing devices (ADDDs). The adopted rules outline the requirements for installation and use of ADDDs in various facilities identified in Chapter 246-874 of the Washington Administrative Code (WAC). Additionally, the adopted rules no longer require facilities to obtain approval from the Commission before using an ADDD. The permanent rules were filed on March 7, 2017, and become effective on April 7, 2017. Pharmacies and nonresident pharmacies must submit a list of physical address locations where they manage or service ADDDs on a form provided by the Washington State Department of Health. This form will be available on the Commission's website by the end of April. Pharmacies currently approved by the Commission to use ADDDs have one year from the effective date of the rule to come into compliance with the new rule, which includes submitting the list of physical locations mentioned above.

No. 1252 Pharmacy Assistant Registration and Fee Reminder

Pharmacy assistant registration fees changed beginning March 1, 2017, as a result of a new rule adopted by the Department of Health in January 2017. The $25 fee will be phased in to match the renewal notice schedule. New pharmacy assistant applicants will pay a $25 fee starting on March 1, 2017. From March 1 until May 31, 2017, renewals for registered pharmacy assistants will be updated to the annual registration cycle, because the renewal notice did not include the fee change. Starting on March 1, 2017, renewal notices inform registered pharmacy assistants of the $25 fee and the annual renewal cycle. After June 1, 2017, all new and renewed pharmacy assistant registrations will incur a $25 registration fee. Any registered pharmacy assistant who renews an expired registration after June 1, 2017, will incur a $25 registration fee, a $25 late fee, and in the case of reactivation of a registration, a $25 reactivation fee.

No. 1253 Tamper-Resistant Prescription Paper

The Commission has put its seal of approval on an updated solution designed to ensure prescriptions' security and validity. The change acknowledges that plain paper printing solutions, which comply with the security characteristics of tamper-resistant prescription paper as state law requires, can be approved for use in Washington State. This change went into effect on March 1, 2017.

In considering plain paper printing solutions, the Commission recognized an opportunity to update its seal of approval. The seal of approval identifies prescription paper and pads that include one or more industry-recognized features to prevent unauthorized copying, erasure or modification, and counterfeiting. Unless otherwise exempted by law, all prescriptions written in Washington State for dispensing by a pharmacist must be written on Commission-approved tamper-resistant prescription paper with the seal.

Vendors must receive Commission approval of tamper-resistant prescription pads, paper, or plain paper printing solutions before engaging in marketing or sales in Washington State. The Commission grants authority to use its seal of approval only to those entities whose prescription paper, pads, or plain paper print solutions are approved.

The updated design of the seal is comparable to the original that was introduced in 2010, with one significant change. The new seal will still include the mortar and pestle as an artificial watermark and an outline of the state map, but it will no longer require green thermochromic ink. The Commission hopes this change will reduce the cost of printing.

Stock of the previously approved seal may be used up before switching to the new seal.

Please visit the Commission's website for more information or contact the Commission at WSPQAC@doh.wa.gov.

No. 1254 Inspections Process

At the March 30, 2017 meeting, the Commission considered draft inspection rule language to move forward with filing

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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.

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a CR-102 form, the next step in the rules process. Further updates will be sent via the Commission's listservs.

No. 1255 Washington Health Workforce Survey

The Department of Health has rolled out a survey of pharmacists, interns, and technicians in Washington to improve the Department's understanding of Washington's health care workforce. The Washington Health Workforce Survey will help answer questions such as, "Are you working?", "Where are you working?", and "What is your area of specialty?" Collecting this information will help promote the surveyed professions and aid the Department's knowledge of the health care workforce.

The Commission helped the Department on this survey and believes the information will be helpful in health care workforce planning. The Department knows health care providers are busy, so the survey was made as short as possible. The majority of the questions are yes/no or multiple choice answers. This is an ongoing survey that providers will be asked to complete each time they renew their credential. For more information on the goals of the survey and how the data will be used, visit the Washington Health Workforce Survey page.

Please take the Washington Health Workforce Survey when you renew online or from the surveyed professions list on the Department's website!

No. 1256 New Pharmacy Commission Staff

Tracy West has joined the Commission staff as rules coordinator. She will coordinate the large rules workload. Tracy has worked for the Department of Health since October 2015, most recently in the Office of the Assistant Secretary, including assisting the Commission with rules. Tracy is a licensed attorney in Massachusetts and Washington. She received her law degree in 2014 from New England School of Law in Boston, MA, and got her bachelor of arts degree from the University of New Mexico in 2007 (she is originally from New Mexico). Before law school, Tracy worked for United States Representative Ben Luján in New Mexico and in his Washington, DC office, giving her experience in legislative writing. Her work with the Commission has helped with the recent adoption of the new pharmacy technology rules.

Shelley Feldner-Schuerman joined the pharmacist investigator team in the Department of Health Office of Investigation and Inspection. She received her doctor of pharmacy degree from Washington State University. Since graduating, Shelley has worked in independent, chain, and rural hospital pharmacy settings. She holds pharmacist licenses in Idaho, Montana, and Washington, and is a licensed pharmacist preceptor in Washington. Shelley lives in a rural setting with her family and enjoys camping and riding horses. Shelley will have primary responsibility for the newly created Area 11 centered around the Tri-Cities.

Daniel Lari also joined the pharmacist investigator team. He received his doctor of pharmacy degree from the University of New Mexico. Since graduating, Daniel has worked in community retail, specialty, and hospital pharmacy settings. Daniel holds pharmacist licenses in both New Mexico and Washington. Outside of work, Daniel enjoys biking, hiking, photography, and traveling. Daniel will have primary responsibility for Area 05 centered in downtown Seattle, WA.

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.

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