June 2017

West Virginia Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

2310 Kanawha Blvd E • Charleston, WV 25311 • *www.wvbop.com*

New Immunization Authority Is on the Horizon, But Still Some Time Away

The West Virginia Legislature passed and Governor Jim Justice signed House Bill (HB) 2518, which will allow pharmacists and pharmacy interns to do more immunizations, after rulemaking on the subject. First, the new statutory provision allows for the legislative rules to add human papillomavirus (HPV) to the list of vaccines that pharmacists can administer to someone age 18 and over. Second, it will allow pharmacists to administer HPV and influenza immunizations to minors age 11 to 18, with a physician's prescription and parental consent. Prior to this bill's passage, by statutory restriction, no immunizations could be given by a pharmacist or pharmacy intern to anyone under age 18. The immunization rules will have to be modified through joint rulemaking with the West Virginia Board of Medicine and the Board of Osteopathic Medicine to take into account this new statutory authority, and then be approved by the Legislature next year. So, if all goes well, this should be in place this time next year.

Retirements and New Hires at the Board

The West Virginia Board of Pharmacy regrets to announce that after many years of service to the Board, Betty Jo Payne and Brenda J. Knoth have both retired from the office staff, and Inspector Dave Gerkin has retired from his inspector's position. The Board thanks them for their loyal service and wishes them well in their retirement. They will be missed.

The Board hired John P. Smolder as its new chief financial officer/chief operating officer. John, an accountant with additional financial and technology background, comes with a variety of state experience and has hit the ground running since he started in early March. In addition, the Board has hired Tina Roberts to work in the Board's licensing and administration department. She comes with several years' experience with a sister-state agency, prior experience in medical offices, and other experience volunteering in her community. With regard to inspectors, the Board had two openings and hired Patrick Regan, RPh, and Thomas Robinette, RPh, to fill those positions. Both also started training in early March and are already out on the circuit inspecting pharmacies and other Board-licensed or registered entities. Welcome, new members of the staff.

Thank You for Helping to Get the Word Out for the April 29, 2017 DEA Take-Back Event

On Saturday, April 29, 2017, Drug Enforcement Administration (DEA) hosted another annual national take-back initiative. For many communities in West Virginia, residents do not have access to dispose of prescription medication other than by throwing the medication in the trash. This event gave residents an opportunity to safely dispose of unused or expired prescription medication in drop boxes. The Board sent out a fax-blast to pharmacies about the event, and it extends thanks to all those who posted a DEA flyer and otherwise notified customers about it so they could take advantage of the opportunity.

Unwanted Drug Take-Back Options

One of the recent calls fielded by a Board inspector was from a patient who stated that when she asked her local pharmacist about what to do with unwanted prescription medication, she was advised to wait for the next National Prescription Drug Take-Back Day. While it is true that this is one option, the pharmacist failed to tell the patient about three other options. Many local and state police and county sheriff offices maintain a take-back box in their central offices. You could inquire of your local facilities to see if they offer that option.

In addition, for take-back days, the West Virginia Attorney General's Office has compiled a handout that lists temporary and permanent drop box locations by county. If you would like the list of participating locations in your area, please contact Liz Grant at 304/267-0239 or elizabeth.d.grant@wvago.gov. The Attorney General's Office is happy to provide this handout to you.

The third option is that DEA permits pharmacies and hospitals to register as take-back agencies. There is no charge for this registration, but pharmacies and hospitals must apply for take-back status with DEA. They must also demonstrate how they will conduct the in-store take-back to show the secure method of storing drugs until being transferred for destruction. Information on this option is available at *https://apps.deadiversion.usdoj.gov/webforms2/spring/disposalLogin?execution=e2s1*.

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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Inspector's Note to Help With Compliance: Employee Listings

Attention pharmacists-in-charge (PICs): Keep your Combined Employee Listing and Confidentiality Statement up to date. As a suggestion, it might be a good idea to prepare a new one every July 1, as it is very likely that at least one employee will have a license expiring on June 30 of every year. It should also be updated any time you have either lost or hired a new employee. Be sure to submit a copy by fax or mail to the Board office. Remember also that it is to be posted in a conspicuous place in the pharmacy department. Likewise, all pharmacists, interns, pharmacy technicians, and pharmacy technician trainees are to have their Board credential posted in the pharmacy. If there are any who do not have it posted, it is ultimately the responsibility of the PIC to make sure this is done.

Some Highlights of Rules Revisions to Title 15, Series 1

HB 4340 (2016) made changes requiring the Board to require national criminal background checks on applicants being licensed to practice pharmacist care for the first time in West Virginia. Therefore, the Board made rules revisions to account for the new requirement for pharmacists and interns. As of April 28, 2017, the changes to the Board's rules became final, and starting July 1, 2017, the rules will require new interns and new pharmacists to go through the same background check process that new pharmacy technician trainees and new pharmacy technicians now go through.

In addition, the Board modified the provisions of §15-1-14.7.5 to permit prescriptions to be delivered to the patient at the location designated by the patient or the patient's designated agent, as the prior language limited dispensing only to the patient's "residence or similar place." This allows for specialty medications and other prescriptions to be delivered to the practitioner's office where they will be administered and also allows the patient to have control over where prescriptions are delivered.

Newsletter to Go Fully Electronic in the Future

In concert with the Board's *Newsletter* partner, the National Association of Boards of Pharmacy Foundation®, and in an effort to modernize the delivery method, this is the last print version of the *West Virginia Board of Pharmacy Newsletter.* All future editions will be provided as downloadable pdfs posted on the National Association of Boards of Pharmacy® (NABP®) website, *www.nabp.pharmacy.* The *Newsletters* have been made available that way for a number of years and are very easy to find on NABP's site. They are also available through a link on the Board's website, *www.wvbop.com.* 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 NABP contact page in the Boards of Pharmacy section of the NABP website at *www.nabp.pharmacy* and click on the subscribe link. The Board is undertaking this effort to deliver updates as timely as possible and make information more easily accessible.

The *West Virginia Board of Pharmacy News* is published by the West Virginia 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.

West Virginia Board of Pharmacy
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