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Wyoming State Board of Pharmacy News

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The Board Welcomes New Inspector/ Compliance Officer, Patrick Johnson, MPH, PharmD, RPh

The Wyoming State Board of Pharmacy welcomes a new addition to the team, Patrick Johnson, MPH, PharmD, RPh. Patrick will serve as one of the Board's inspectors/compliance officers. He graduated with his pharmacy degree from the University of Kansas, and his background includes a diverse range of retail/clinical practice sites and pharmaceutical drug development.

After initially working for Walgreens in Oregon, Patrick decided to pursue a master's degree in public health (MPH) at the University of South Florida. While working on this degree, he provided temporary relief services to Indian Health Service outpatient clinics in the areas of intravenous infusion, mental health, detoxification addiction services, and diabetes management.

Upon completion of his MPH in tropical and neglected diseases, Patrick was hired by a biotechnology company in the District of Columbia metro area. The program focused on the pre-clinical development of a broad spectrum antiviral for acute conditions such as dengue fever and influenza. After spending two-and-a-half years on the project, the company successfully completed Food and Drug Administration's Investigational New Drug Application, taking the medication into Phase 1 clinical trials. At this point, Patrick left the District of Columbia and returned to pharmacy practice. He joined the Board after spending the last two-and-a-half years working at the Colorado State University Health Network Pharmacy in Fort Collins, CO.

Patrick began with the Board on March 1, and he enjoys the opportunity to utilize both his pharmacy practice background and public health background on a daily basis. As the profession evolves and adapts to changing health and practice needs, he looks forward to addressing those challenges with his new coworkers. He plans on exploring Wyoming's scenic towns, hiking trails, and disc golf courses, as the needs of his position take him out on the road.

Transitioning From Technician-in-Training to Pharmacy Technician

There is always a big push to get technicians-in-training to take the Pharmacy Technician Certification Board (PTCB) examination or the Exam for the Certification of Pharmacy Technicians (ExCPT), so that they can be certified. Unfortunately, many technicians-in-training and pharmacists-in-charge fail to remember that even if a technician-in-training has passed the examination, he or she is not licensed as a pharmacy technician by the Board. Until licensed, they are only allowed to perform the functions of a technician-in-training as listed in Chapter 10, Section 7 of the Wyoming Pharmacy Act.

In order to be licensed as a pharmacy technician, an individual must submit the following items.

- An application for licensure
- License fees
- Fingerprint cards
- A PTCB or ExCPT certificate
- A passport-sized photograph
- A certified copy (notarized or original) of his or her birth certificate or passport
- A certified copy of a high school diploma, GED certificate, or college transcript

Any original documents that are provided will be returned.

The Board does not issue the license for a pharmacy technician until all of the items have been provided to the Board office, and the results of the criminal background check are received. It can take two to six weeks for the Board to receive the results of the background check.

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National Pharmacy Compliance News

June 2019

NABPF
National Association of Boards of Pharmacy Foundation

The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

FDA Launches Pilot Program to Improve Security of Drug Supply Chain With an Innovative Approach

Food and Drug Administration (FDA) has launched a pilot program allowing participants representing the various parts of the drug supply chain to pilot innovative and emerging approaches for enhanced tracing and verification of prescription drugs in the United States' supply chain. The program is in line with FDA's ongoing efforts to prevent suspect and illegitimate products from entering the supply chain, according to an FDA press release. Eligible manufacturers, repackagers, and other stakeholders can apply to participate in the program, which will inform the development of the enhanced electronic, interoperable track-and-trace system for industry set to go into effect in 2023 in accordance with the Drug Supply Chain Security Act (DSCSA), enacted by Congress on November 27, 2013.

The pilot technologies of this program may become part of FDA's enhanced expectations for reliable track-and-trace systems, which will be designed to reduce diversion of drugs distributed domestically and to keep counterfeit drugs from entering the supply chain. The DSCSA pilot project program is intended to help identify and evaluate the most efficient processes to comply with and apply drug supply chain security requirements and will aid in identifying attributes the system will need for enhanced product tracing and verification, as well as electronic means to share the information. FDA recently issued draft guidance on the use of product identifiers with a unique serial number to improve verification down to the package level. FDA has also provided draft guidance for verification systems to quarantine and investigate suspect and illegitimate drugs.

Additional information on the FDA pilot program is available in a February 8, 2019 announcement in the *Federal Register.*

FDA Announces New Efforts to Increase Oversight and Strengthen Regulation of Dietary Supplements

Noting that three in four Americans now take at least one dietary supplement on a regular basis, and that the dietary supplement industry has expanded to include as many as 80,000 different products for consumers, FDA Commissioner Scott Gottlieb, MD, has announced new plans to increase the agency's oversight of dietary supplements. These initiatives include communicating to the public as soon as possible when there is a concern about a dietary supplement on the market, ensuring that the regulatory framework is flexible enough to adequately evaluate product safety, and continuing to work closely with industry partners. FDA is also developing new enforcement strategies to respond to entities that violate standards established under the Dietary Supplement Health and Education Act of 1994.

On February 11, 2019, FDA sent 12 warning letters and five online advisory letters to foreign and domestic companies that are illegally selling more than 58 products. The products are illegally marketed as unapproved new drugs that make unproven claims about preventing, treating, or curing Alzheimer's disease, as well as a number of other serious diseases and health conditions, such as diabetes and cancer. In his statement, Gottlieb noted that most stakeholders in the industry act responsibly, but he expressed concern over the ability of bad actors to exploit the system by providing potentially dangerous products and making unproven or misleading claims about the health benefits supplements may offer.

FDA is planning a public meeting on this topic during the second quarter of 2019. For more information, view the FDA statement at *https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm631065.htm.*

Trump Administration Releases National Drug Control Strategy to Reduce Drug Trafficking and Abuse

As the opioid crisis continues to claim the lives of tens of thousands of Americans each year, the Office of National Drug Control Policy has released its *National Drug Control Strategy.* The *Strategy* breaks down the administration's priorities in addressing the crisis, with an emphasis on three areas: prevention, treatment and recovery, and reducing availability.

- **Prevention** efforts are focused on educating both consumers and caregivers about the dangers of opioid misuse and include a new national media campaign, continued efforts to expand prescription monitoring programs (PMPs), and improving the ability of state, local, and tribal communities to identify and prevent substance abuse.
- **Treatment and recovery recommendations** in the *Strategy* include improving access to naloxone, improving evidence-based addiction treatment, and eliminating barriers for accessing treatment.

- **Reducing availability** strategies are focused on disrupting illegal supply chains, defeating drug traffickers, increased cooperation with international partners, and combating illegal internet drug sales.

The document notes that the "most important criterion of success" is saving lives and calls for the federal government to work closely with state and local governments, as well as other stakeholders. Additional information, including the full strategy document, is available on the White House website at *https://www.whitehouse.gov/opioids.*

National Association of Boards of Pharmacy® (NABP®) and its member boards of pharmacy remain committed to advancing best practices for PMPs in the interest of public health. NABP's PMP data sharing system, NABP PMP InterConnect®, facilitates the secure transfer of PMP data across state lines and provides an effective means of combating drug diversion and drug abuse nationwide. In addition, NABP and its member boards continue efforts to educate consumers about prescription drug safety. The NABP $AWAR_XE$® Prescription Drug Safety Program's Drug Disposal Locator Tool has more than 6,000 disposal locations and continues to add new locations to provide consumers with a safe way to dispose of medication and help prevent misuse and abuse of prescription medications. For more information about PMP InterConnect and the $AWAR_XE$ program, visit the Initiatives section of the NABP website at *www.nabp.pharmacy.*

New Study Predicts Opioid Epidemic Will Worsen Over the Next Decade

More than 700,000 people will die from opioid overdoses between 2016 and 2025, and annual overdose deaths will reach nearly 82,000 by 2025, estimates a new study published to *JAMA Network Open.* The estimate is based on an analysis of data from the National Survey on Drug Use and Health and the Centers for Disease Control and Prevention from 2002 to 2015.

Researchers also projected that intervention efforts focused on lowering the incidence of prescription opioid misuse would help to reduce the number of deaths 3.8% to 5.3%, a figure the researchers described as "modest," due to the changing nature of the opioid crisis. The study notes that more people are directly initiating opioid use with illicit opioids rather than prescription drugs, and illicit opioids have become more lethal with the availability of illegally manufactured fentanyl.

The researchers encourage policymakers to take "a stronger and multipronged approach" to reduce the impact of the ongoing opioid overdose epidemic. The full article is available at *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2723405.*

FDA Warns of Potential Blood Pressure Medication Shortages Due to Recalls

FDA is warning health care providers and consumers of a shortage of angiotensin II receptor blockers, commonly used to treat high blood pressure. A growing list of medications containing valsartan, losartan, and irbesartan have been recalled from the market for containing an impurity that may present a cancer risk to patients. The issue was first detected in the summer of 2018, according to a statement posted to the FDA website. Since then, FDA has placed a Chinese manufacturer of the active ingredient on import alert to stop their imports, and FDA is working with other manufacturers to recall affected medications.

In the statement, FDA notes that the risk to individual patients remains very small, but that there is still reason to be concerned about the potential health risks. Medications with these impurities are believed to have been in the market for about four years.

"Now that these risks are identified, we're applying what we've learned to the evaluation of similar manufacturing processes where we now know these risks could arise," the statement notes. The FDA press release is available at *https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm629796.htm.*

FDA Releases Two Draft Guidances Related to REMS Programs

FDA has released two new draft guidances to ensure risk mitigation programs put in place for certain drugs and biologics, as required for approval, are working. The agency's primary risk management tool is FDA-approved product labeling. However, in limited cases, FDA may require a Risk Evaluation and Mitigation Strategy (REMS) to help ensure a drug's benefits outweigh its risks.

The following guidances relate to the assessment of REMS programs:

- **REMS Assessment: Planning and Reporting Guidance for Industry** describes how to develop a REMS Assessment Plan.
- **Survey Methodologies to Assess REMS Goals That Relate to Knowledge Guidance for Industry** provides recommendations on conducting REMS assessment surveys to evaluate patient or health care provider knowledge of REMS-related information.

FDA states that the goal in providing this guidance for REMS is to ensure constant improvement of their safety programs and establish the most efficient and effective programs moving forward, to optimize patient care and keep consumers safe and healthy. More information on REMS is available on the FDA website at *https://www.fda.gov/drugs/drugsafety/rems.*

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It is important to be cognizant of the date that the permit of a technician-in-training expires. This ensures that the application for licensure as a pharmacy technician is submitted early enough to allow the technician-in-training to continue to work in that capacity until the license is issued.

Compliance Corner: Focus of Inspections in 2019

The focus of inspections in 2019 includes the following items.

- Schedule II perpetual inventory reconciliation for both the annual controlled substance (CS) audit and the requirement to perform a quarterly reconciliation
- Demonstration of the ability to access the Wyoming Online Prescription Database, including an audit of CS prescriptions dispensed from the pharmacy
- Written agreements between pharmacies and long-term care facilities (as either a provider pharmacy or first-dose pharmacy) providing first-dose services
- Labeling of unit-dose packaging (bubble packs) with required information
- Documentation of training and compounding competencies for compounding staff (both sterile and nonsterile)
- Review of the master compounding record for nonsterile compounding, including reconciliation of ingredients for any compounding
- Demonstration of the ability to access and update immunization information in the Wyoming Immunization Registry
- Posting a current CPR certification for immunizing pharmacists and an emergency protocol for anaphylaxis
- Maintaining the required emergency kit for anaphylaxis
- Any other issue identified during the previous inspection

Sterile Compounding Update

The Board voted at its March 2019 meeting to have the compliance officers inspect to the May 2017 version of United States Pharmacopeia (USP) General Chapter <797> for compliance until July 1, 2020. Inspections for sterile compounding pharmacies will continue to use the National Association of Boards of Pharmacy® Multistate Pharmacy Inspection Blueprint Program's Universal Inspection Form — Sterile Compounding Module and will still require more time to complete. The compliance officers will gown and garb to enter the cleanroom to observe sterile compounding and to inspect the facility for compliance. To prepare for the inspection, be sure to complete a self-inspection in advance. Sterile compounders should be reviewing the July 27, 2018 version of USP General Chapter <797> (available from the Board) to identify and plan for remodeling, as appropriate for their practice.

2019 Wyoming Legislative Update

Senate File (SF) 0046 – Opioid prescription limits (Effective July 1, 2019)

The following subsection was added to Wyoming Statute (W.S.) 35-7-1030.

(e) No practitioner shall prescribe nor shall any person dispense any opioid or combination of opioids for acute pain to an opioid naive patient for more than a seven (7) day supply in a seven (7) day period. The board shall by rule establish reasonable exceptions to this section, in consultation with other professional licensing boards that license practitioners, including exceptions for chronic pain, cancer treatment, palliative care and other clinically appropriate exceptions. As used in this subsection:

i. "Opioid" means an opiumlike compound that binds to one (1) or more of the major opioid receptors in the body;

ii. "Opioid naive patient" means a patient who has not had an active opioid prescription in the preceding forty-five (45) day period.

SF 0047 – Controlled substances education and administration (Effective July 1, 2019)

Part of W.S. 33-24-121 was amended to read:

The board shall require one and one-half (1 ½) hours of continuing education related to the responsible prescribing of controlled substances annually.

Part of W.S. 35-7-1030 was amended to read:

(e) On and after January 1, 2021, except when dispensed directly by a practitioner other than a pharmacy to an ultimate user, no controlled substance included in any schedule shall be dispensed without the electronic prescription of a practitioner. The prescription for a controlled substance included in Schedule III or IV shall not be filled or refilled more than six (6) months after the date of the prescription or be refilled more than five (5) times unless renewed by the practitioner. The board may by rule and regulation provide exemptions from the requirements of this subsection including exemptions for emergencies and technical failures.

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Part of W.S. 35-7-1060 was amended to read:

(b) Except as otherwise provided in this subsection, when a practitioner, other than a veterinarian, prescribes a schedule II, III, IV or V controlled substance, the practitioner or his delegate shall search the prescription tracking program for prior prescriptions issued to the patient before first issuing the prescription and shall repeat the search every three (3) months thereafter for as long as the controlled substance remains a part of the patient's treatment. A practitioner who prescribes a schedule V controlled substance shall only be required to search the program as otherwise provided in this subsection if the substance is an opioid.

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