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News

Wyoming State Board of Pharmacy

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New Board Member, Tim Seeley, RPh

Timothy S. Seeley was appointed to the Wyoming State Board of Pharmacy by Governor Matt Mead in May 2017. Tim is a past president of both the Wyoming Pharmacy Association and the Wyoming Society of Health-System Pharmacy. He was the pharmacist-in-charge (PIC) at Powell Valley Healthcare and at Hot Springs County Memorial Hospital and is currently the PIC at South Big Horn County Hospital. Tim has received numerous awards, including the Excellence in Innovation Award in 1994, Wyoming Health System Pharmacist of the Year in 2000 and 2008, Wyoming Pharmacist of the Year in 2008, and the most prestigious award, the Bowl of Hygeia, in 2013.

Board Meeting Date Change and Public Hearing

The next Board meeting is September 20-21, 2017, at 500 South 3rd St, Laramie, WY, 82070, beginning at 1 PM on Wednesday, September 20, in the meeting room of the Board of Professional Geologists. A public hearing on proposed rules changes will be held beginning at 9 AM on Thursday, September 21 at the same address. The Board of Pharmacy proposes to amend Chapters 2, 8, and 14 of the Wyoming Pharmacy Act (WPA) Rules and Regulations. The amendments update definitions, formatting, and grammar, as well as revise regulations for distributors of prescription drugs, electronic record keeping, transfers of prescriptions, fees, and late fees for new types of distributors, and processes during closure of a pharmacy. Telepharmacy regulations are revised based on legislation passed in 2017. A new Chapter 18 has been adopted under Emergency Rules for 120 days, describing the requirements for pharmacists to prescribe naloxone as a rescue medication for opiate overdoses. Comments can be submitted to BOP@wyo.gov on or before 5 PM on September 19, 2017. The proposed rules are posted on the Wyoming Secretary of State website at *https://rules.wyo.gov* and can also be obtained by emailing BOP@wyo.gov. A Board meeting is also scheduled for December 6-7, 2017, at 2211 King Blvd, Casper, WY, in the Oil and Gas Commission building, beginning at 1 PM on Wednesday, December 6, 2017.

Pharmacists Can Now Prescribe Naloxone

By Amy Thompson, PharmD Candidate

Expanding access to naloxone is critical in decreasing mortality related to the opioid epidemic. Because pharmacists are considered by many to be the frontline of health care, they have the potential to not only provide education on the use of naloxone, but to drastically increase the community's access to the lifesaving drug.

Wyoming pharmacists have been presented with a unique opportunity to better serve our communities with the passage of the new Emergency Administration of Opiate Antagonist Act. Pharmacists now have the authority to prescribe naloxone in an effort to expand naloxone access to members of the community who are at highest risk of experiencing or witnessing an opioid-related overdose. As of July 17, 2017, the Board has adopted new emergency rules concerning naloxone prescribing, which can be found in Chapter 18 of the WPA Rules and Regulations. A few highlights from the new rules are listed below:

- Pharmacists can prescribe naloxone without a prescriber-patient relationship to people at risk of experiencing an opioid-related overdose and to people who may be in a position to assist someone experiencing an opioid-related overdose.
- Prior to prescribing naloxone, pharmacists must successfully complete one hour of continuing education specific to the use of naloxone.
- Pharmacists must provide counseling on each naloxone prescription dispensed. Refer to Chapter 18 for a list of the required counseling points.
- A written or electronic prescription must be generated for all naloxone prescriptions that lists the dispensing pharmacist as the prescriber.
- All prescriptions for naloxone must be reported to the prescription drug monitoring program, the Wyoming Online Prescription Database (WORx), by the close of business on the day immediately following the date the naloxone was dispensed.

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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.ncpdp.org/NCPDP/media/pdf/NCPDPEmergencyPreparednessInformation_v1_4.pdf.* Additional information for pharmacists about emergency preparedness is available on the NCPDP website at *www.ncpdp.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®, Efudex®, and

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.*

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While it is important that pharmacists continue to counsel all patients taking opioids about the dangers associated with opioid use, they can now provide high-risk patients (such as chronic pain or cancer patients who are on large daily doses of opioids) with this lifesaving drug to use in the event of an accidental overdose. *Prescribetoprevent.org,* along with many other websites, is a great resource tool that pharmacists can use to educate themselves on different naloxone formulations and their respective administration. There are also several resources listed on the Board's website, including a patient-centered naloxone brochure, a sample naloxone prescription for pharmacists, and a detailed summary of Chapter 18.

Rules Revisions Signed by Governor on May 17, 2017

WPA Rules Chapters 1, 15, 16, and 17 were revised and adopted by the Board following a public comment period and hearing on March 29, 2017. Changes to Wyoming Controlled Substances Act (CSA) Rules Chapters 4, 6, 7, and 8 were also adopted and signed by Governor Mead. A summary of the changes is included in this *Newsletter,* and the full strikethrough and underlined versions can be obtained by emailing BOP@wyo.gov.

Wyoming Rules Revisions Signed by Governor Matt Mead on May 17, 2017

Rules WPA Citation	Topic	Change
Chapter 1 - Rules of Practice and Procedure	General	Spelling, numbering, format corrected throughout. Some sections changed numbers.
Chapter 1, Section 9 - Incorporate by Reference	Incorporate by Reference	Uniform rules for contested case hearings. Uniform procedures for requests of public records and fees.
Chapter 15 - Long Term Care Pharmacy Services	General	Changes the term from "patient" to "resident."
Chapter 15, Sections 4 and 9	First Dose Pharmacy	Defines First Dose Pharmacy and how its service is to be provided, including a contract.
Chapter 15, Section 8	Restocking Long-Term Care (LTC) Facility	Requirements for restocking automated dispensing devices by a pharmacist or by a registered pharmacy technician or intern under their supervision, each licensed by the Board.
Chapter 16 - Immunizations	Section 5 - Pneumonia Vaccine	Deletes the word "polysaccharide" so that any pneumococcal vaccine can be administered to healthy adults per Centers for Disease Control and Prevention (CDC) recommendations.
Chapter 16, Section 6	Human Papillomavirus (HPV) Vaccine	Allows a pharmacist to prescribe and administer HPV vaccine to a minor per CDC recommendations.
Chapter 17 - Sterile Compounding	General	Deletes most of the chapter and incorporates by reference to United States Pharmacopeia (USP) Chapter <797>.
Chapter 4 - Records and Inventories	General	Adds "electronic" to specific records required.
Chapter 4	Prescriptions	Records may be kept written or electronic by consecutive numbers or by date.
Chapter 4	Schedule II Order Forms	Drug Enforcement Administration (DEA) 222 or Controlled Substances Ordering System orders and invoices are to be maintained separately from other records and kept for two years as readily retrievable.
Chapter 4	Methamphetamine Precursor Records	Revises requirement for photo identification and how logbooks shall be kept.
Chapter 6 - Prescriptions for Controlled Substances	Definitions	Revised and updated. "Oral" changed to "verbal."
Chapter 6, Section 7	Schedule II Prescriptions	Revised security paper prescription requirements; use of stickers is allowed for patient name but not for drug, strength, quantity, or directions.
Chapter 6, Section 13	Emergency Schedule II Prescription	Report to DEA if the written prescription is not provided by the practitioner within seven days.
Chapter 6, Section 16	Partial Fill Schedule II	Allowed for LTC or terminally ill patients for up to 60 days from issue date.
Chapter 7 - Administrative Inspections	General	Incorporate by reference to Code of Federal Regulations Part §1316.01 to 1316.13 as of July 17, 2015.
Chapter 8 - WORx	Updates to 2015 Statute Changes	24-hour reporting, adding payment method, rules for delegates.
Chapter 8 - WORx	Reporting of Noncontrolled Drugs	Requires reporting of dispensing of gabapentin, cyclobenzaprine, and naloxone.

Clarification on Transfers of Unfilled EPCS

The National Association of Boards of Pharmacy® and DEA have provided information on transfers. DEA policy is found in the preamble of the interim final rule on Electronic Prescriptions for Controlled Substances (EPCS), 75 *Federal Register* 16235. As posted in the preamble, an unfilled original EPCS can be forwarded from one DEA-registered retail pharmacy to another DEA-registered retail pharmacy, and this includes Schedule II controlled substances.

USP Chapter <800> Hazardous Drugs

By Lisa Hunt, Compliance Officer

Many pharmacists think the new USP Chapter <800> regarding hazardous drugs applies only to institutional or sterile compounding pharmacies. However, there are drugs listed as hazardous that are routinely dispensed by community pharmacies, such as spironolactone, tamoxifen, fluconazole, warfarin, and methotrexate. USP Chapter <800> applies to all entities that store, prepare, transport, or administer hazardous drugs listed by the National Institute for Occupational Safety and Health. Personnel need to be trained, and policies will need to cover receiving, labeling, packaging, transport, and disposal as well as compounding, dispensing, and deactivating. Protection for health care workers and the work environment, including spill control, must be part of the policy. USP Chapter <800> becomes effective on July 1, 2018, as a standard and is being discussed during this year's inspections.

Hank York, RPh, Retirement

Hank York came to the Board as an inspector/compliance officer in 2003 and has been traveling the state for 14 years. He retired in June 2017, and the Board members and staff expressed their appreciation for his years of service and expertise. Hank is planning to spend time in Douglas, WY, as well as Helena, MT, during retirement. A reception was held at the Board office in April 2017, and Hank thanks all for their many kind cards, emails, and good wishes.

The *Wyoming State Board of Pharmacy News* is published by the Wyoming State Board of Pharmacy and the National Association of Boards of PharmacyFoundation® (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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