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News

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Focus of Inspections for 2017

By Lisa Hunt, RPh, and Hank York, RPh, Wyoming Compliance Officers

Perpetual Inventory Reconciliation

Inspectors are seeing more and more pharmacies using electronic inventories. Remember that even if your pharmacy has gone to an electronic perpetual inventory, a report must be available on site that explains any edits or changes to the inventory.

WORx Report Usage

Do not be surprised if during this year's inspection, your inspector asks you how it is going using the Wyoming Online Prescription Database (WORx). Inspectors are trained on WORx report generation and will be available to answer your questions about this program.

Connectivity to WyIR

The Wyoming Pharmacy Act Statute 33-24-157(a) states that "A pharmacist administering vaccinations pursuant to this section shall enter a record of the immunization in the Wyoming immunization registry [WyIR] operated by the department of health." This means that immunizing pharmacists must have access to WyIR. Use of WyIR to check a patient's previous immunization record is important and may provide an opportunity to prescribe other vaccines. Inspectors will be checking to make sure your pharmacy immunizers have this connectivity.

Long-Term Care Facility Agreements

Wyoming rules require an agreement between a pharmacy and a long-term care facility if the pharmacy provides services for the residents. Make sure your agreements are up to date for 2017.

Sterile and Nonsterile Compounding

Wyoming State Board of Pharmacy inspectors will be checking for both United States Pharmacopeia Chapter <797> and Chapter <800> preparedness. The new National Association of Boards of Pharmacy® (NABP®) sterile compounding inspection form will be used for sterile compounding inspections. Plan on increased time spent during the inspection and any follow-up.

Compounding Competency Records

Now is a good time of year to make sure all of your pharmacy staff compounders have their compounding competencies completed for 2017 and on file for inspection.

Patient Safeguards

What is your pharmacy implementing this year to increase patient safety? Does your pharmacy use a triple-check system or show-and-tell counseling? Does your final check include going back to the source bottle label and verifying against the received prescription? This is where you report to your inspector your improvement plans for 2017.

Thank You to John McPherson, DDS

John McPherson, DDS, is leaving the Board. Dr McPherson was appointed to the Board in 2005 and was reappointed in 2011, serving a full 12 years. He served as secretary-treasurer and on several committees. The Board appreciates Dr McPherson's service and commitment, especially because he practices dentistry in Laramie, WY, and had to plan ahead for meetings as well as for patient appointments. He was presented with an engraved mortar and pestle as a thank you for a job well done.

Recent Disciplinary Actions

Pharmacy License #R10071: Administrative penalty of $2,500 each for unlicensed practice by pharmacists, outdated products, medication errors, and incorrect substitution of non-AB-rated generic products. Total fine of $10,000, plus plans to prevent future such violations.

A.M., Pharmacist License #3604: Letter of admonition for a medication error, requiring five hours of continuing education regarding medication error prevention in addition to the annual requirement, plus a plan to prevent errors.

R.S., Technician-in-Training Permit #TT2405: Voluntarily surrendered due to diversion of controlled substances.

Emergency Contraceptives – Clearing Up the Confusion

By Adrianna Hotchkiss, PharmD Candidate, University of Wyoming School of Pharmacy

On a recent trip to Colorado, I was surprised to come across emergency contraceptive products in the feminine products aisle of the grocery store. Believing that there were age restrictions and that these products had to be sold from behind the pharmacy counter, I decided to do some research to find out what I had missed, and if it only applied in Colorado. As it turned out, I had missed a lot, and apparently I was not the only one. I quickly learned that Plan B One-Step® and generic versions such as Next Choice One Dose® and My Way® have been federally approved by Food and Drug Administration (FDA) as over-the-counter (OTC) products with no age restrictions for quite some time now. However, the evolution of the OTC status of emergency contraceptive products has been a long and complicated journey that left both health care providers and consumers confused. A 2015 survey showed that only 64% of pharmacies stocked emergency contraceptives on the OTC shelves, and 39% imposed an age restriction for purchase.

I went back to the beginning, when Plan B One-Step was first approved by FDA, and followed the product's status from that point to get the full picture:

- July 10, 2009 – Plan B One-Step (manufactured by Teva Pharmaceuticals) New Drug Application is approved as an OTC product for women age 17 or older, with a prescription-only requirement for adolescents younger than age 17.
- February 2011 – Teva submits a supplemental application seeking to remove the prescription-only status for adolescents younger than age 17. The United States Secretary of Health and Human Services (HHS) objects, and FDA denies the application in December 2011.

continued on page 4

National Pharmacy

The applicability of articles in the *National Pharmacy Compliance*
by examining the law of

FDA Issues Final Rule Amending List of Drug Products That May Not Be Compounded

Food and Drug Administration (FDA) issued a final rule amending FDA's list of drug products that may not be compounded under certain sections of the Federal Food, Drug, and Cosmetic Act (FD&C Act) that allow the marketing of unapproved compounded drugs. Drug products on the list may not be compounded because the drug products have been withdrawn or removed from the market for safety or effectiveness reasons, indicates FDA. The list may be found in the Code of Federal Regulations at Title 21, Section 216.24, at *www.ecfr.gov.*

The final rule adds 24 types of drugs to the withdrawn or removed list; modifies the withdrawn or removed list to allow one type of drug product to be compounded under certain circumstances; and clarifies that the withdrawn or removed list applies to sections 503A and 503B of the FD&C Act. The final rule is available at *www.gpo.gov/fdsys/pkg/FR-2016-10-07/pdf/2016-24333.pdf.* FDA provides more information online at *www.fda.gov/Drugs/DrugSafety/ucm524320.htm.*

Selected Medication Risks to Manage in 2017

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.*

Some medication safety risks are painfully apparent in an organization, while many others lie dormant in the system until an error or adverse event draws attention to them. ISMP thought it would be useful to describe selected medication safety risks for organizations to manage in 2017 that might otherwise fall off the radar screen.

Environmental Factors, Workflow, and Staffing Patterns – Poor Quality Lighting

Lighting is a crucial aspect of the physical environment that has been linked to medication safety.[1] Poor quality lighting has often impaired the highly visual tasks associated with medication use, thus leading to medication errors. Examples include tubing misconnections due to low lighting in a patient's room, infusion pumps that have been misprogrammed because of dim backlighting on the screens, and product selection errors in the pharmacy and patient care units caused by low lighting under a pharmacy hood or shadows around an automated dispensing cabinet (ADC).

Despite existing guidelines for lighting in health care, it has been a challenge to implement optimal lighting conditions for prescribing, dispensing, and administering medications. Recent literature reviews found that little system-wide action has been taken to increase staff awareness of the problem or improve the lighting.[1,2] This is largely because the tasks associated with medication use are varied and carried out under diverse physical conditions and in differing locations, and because there are differences in an individual's light requirements based on visual acuity and age. With an ever-increasing population of older health care providers, eye fatigue from computer work and task complexity, small font sizes on medication labels, poor background contrast, and glare or shadows have taken their toll on visual accuracy.[1,2]

Proper illumination improves both the accuracy and efficiency of medication-related tasks. Fluorescent cool white lamps or compact fluorescent lamps should be used in areas where critical tasks are performed, including on mobile medication carts, near ADCs, and in patients' rooms for nighttime administration of medications.[3,4] Administration of medications at night under low lighting to avoid disturbing the patient is an unsafe practice and should be avoided. Adjustable 50-watt high-intensity task lights are recommended when difficult-to-read prescriptions and product labels are encountered.[4] Illumination levels for computer order entry areas should be at least 75 foot-candles (fc), while 100-150 fc are needed when interpreting handwritten orders.[4] Medication preparation areas, medication verification areas, and patient counseling areas should have illumination levels between 90-150 fc.[4] Medication rooms should provide illumination at 100 fc.[4] Lighting levels should be increased if the workforce has an average age above 45 years. A magnifying glass and task light together can also significantly improve accuracy[3] and should be used on mobile medication carts (including those used with bar code medication verification systems)[4] and near ADCs.

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DEA to Decrease Manufacturing Amount of Opioid Controlled Substances in 2017

Drug Enforcement Administration (DEA) is reducing the amount of almost every Schedule II opiate and opioid medication that may be manufactured in 2017 by 25% or more. Other medicines were reduced by more, such as hydrocodone, which will be 66% of last year's level, indicates the DEA news release. DEA notes that demand for these opioid medicines has declined based on sales data from IMS Health, a company that provides insurance companies with data on prescriptions written and prescription medications sold in the United States.

The aggregate production quota (APQ) established by the final order is the total amount of a controlled substance (CS) necessary to meet the estimated medical, scientific, research, industrial, and export needs for the year and for the maintenance

of reserve stocks. The 2017 APQ has been reduced for oxycodone, hydrocodone, fentanyl, hydromorphone, morphine, and other such medications. Much of this reduction is attributed to the elimination of a 25% buffer that was added to the APQ annually in 2013 through 2016 to guard against shortages. The purpose of quotas is to provide an adequate and uninterrupted supply for legitimate medical need of the types of Schedule I and II CS that have a potential for abuse, while limiting the amounts available to prevent diversion.

Additional details may be found in the DEA news release available at *www.dea.gov/divisions/hq/2016/hq100416.shtml* and in the final order available at *https://www.gpo.gov/fdsys/pkg/FR-2016-10-05/pdf/2016-23988.pdf*.

New CDC Brochure Offers Pharmacists Tips for Addressing Prescription Opioid Abuse and Overdose

Centers for Disease Control and Prevention (CDC) released a brochure encouraging pharmacists, who are an essential part of the health care team, to help prevent opioid abuse and overdose. The brochure, "Pharmacists: On the Front Lines," offers tips for communicating with patients who are receiving opioid therapy. In addition, the brochure offers tips on how to identify forged prescriptions and urges pharmacists to maintain collaborative working relationships with prescribers to improve patient outcomes. The brochure is available at *www.cdc.gov/drugoverdose/pdf/pharmacists_brochure-a.pdf*.

FDA Requires Boxed Warnings and Patient-Focused Medication Guides Indicating Serious Risks Related to Combined Use of Certain Opioid Medications and Benzodiazepines

FDA is requiring class-wide drug labeling changes to inform health care providers and patients of the serious risks associated with the combined use of certain opioid medications and benzodiazepines. Specifically, after an extensive review of the latest scientific evidence, FDA is requiring boxed warnings and patient-focused Medication Guides for prescription opioid analgesics, opioid-containing cough products, and benzodiazepines that provide information about the serious risks associated with using these medications at the same time. Risks include extreme sleepiness, respiratory depression, coma, and death.

FDA's news release indicates the changes are part of the agency's Opioids Action Plan, which focuses on policies aimed at reversing the prescription opioid abuse epidemic while providing patients in pain with access to effective and appropriate pain management. The public health crisis is evident through the significant rise of preventable overdose and death associated with the concurrent use of two drug classes, indicates FDA Commissioner Robert Califf, MD, in the press release, available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm518697.htm*.

FDA's Division of Drug Information Offers CE Webinars for Students and Clinicians

FDA's Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information 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 drug shortages and prescription drug promotion. The webinars and presentation slides can be accessed on FDA's website at *www.fda.gov/DDIWebinars*.

FDA Approves Labeling Changes for All Prescription Testosterone Products

In October 2016, FDA approved class-wide labeling changes for all prescription testosterone products regarding the risks associated with abuse and dependence of the drug. The changes include adding a new warning as well as updating the Abuse and Dependence section to include new safety information from published literature and case reports regarding the risks associated with abuse and dependence of testosterone and other anabolic androgenic steroids (AAS). The Anabolic Steroids Control Act of 1990 placed AAS, including testosterone, in Schedule III of the Controlled Substances Act.

Prescription testosterone products are FDA-approved as hormone replacement therapy for men who have low testosterone due to certain medical conditions. However, testosterone and other AAS are abused by adults and adolescents, including athletes and body builders, notes FDA. FDA indicates the new warning will "alert prescribers to the abuse potential of testosterone and the serious adverse outcomes, especially those related to heart and mental health that have been reported in association with testosterone/AAS abuse." In addition, new labeling information in the Warning and Precautions section advises prescribers of the importance of measuring serum testosterone concentration if abuse is suspected.

FDA explains that abuse of testosterone, usually at doses higher than those typically prescribed and usually in conjunction with other AAS, is associated with serious safety risks affecting the heart, brain, liver, mental health, and endocrine system. Reported serious adverse outcomes include heart attack, heart failure, stroke, depression, hostility, aggression, liver toxicity, and male infertility. Individuals abusing high doses of testosterone have also reported withdrawal symptoms, such as depression, fatigue, irritability, loss of appetite, decreased libido, and insomnia. The FDA announcement is available at *www.fda.gov/Drugs/DrugSafety/ucm526206.htm*.

Latest FDA Drug Info Rounds Training Videos Available

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, "Extortion Scam," pharmacists discuss steps a potential victim could take if they receive a call from individuals posing as FDA and DEA agents. Drug Info Rounds is developed with contributions from pharmacists in FDA's 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*.

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continued from page 1

- April 5, 2013 – The US District Court in New York orders the FDA Commissioner of Food and Drugs and the US Secretary of HHS to grant the Citizen Petition to make levonorgestrel-containing emergency contraceptives available OTC without age or point-of-sale restrictions. To comply, FDA asks Teva to submit a supplemental application seeking approval for Plan B One-Step to be made available without any restrictions.
- April 30, 2013 – FDA approves an amended application submitted by Teva to market Plan B One-Step for use without a prescription by women and adolescents 15 years of age and older.
- June 20, 2013 – FDA approves Teva's supplemental application, with nonprescription use of Plan B One-Step without age or point-of-sale restrictions. Teva gains three-year exclusivity for removal of all point-of-sale restrictions and nonprescription use.
- February 25, 2014 – FDA sends a letter to Teva competitors stating that generics may be sold OTC to all ages; however, their labeling during the exclusivity period must state that their products are intended only for women age 17 and older.
- April 30, 2016 – Teva's exclusivity expires, and generic packaging no longer must be labeled as intended only for women age 17 and older.

After going through the full timeline, it was clear why there is confusion. Teva's exclusivity rights added the requirement for generic versions to label their products as intended for women age 17 and older. Seeing this on the label, pharmacists and consumers alike were unsure of the right for adolescents under the age of 17 to purchase the products without a prescription. With the expiration of Teva's exclusivity on April 30, 2016, these labeling requirements are gone.

Notice of Public Hearing Regarding Rules Revisions

The Board is proposing rules revisions under the Wyoming Pharmacy Act Rules Chapters 1, 2, 8, 15, 16, and 17 and under the Wyoming Controlled Substances Act Rules Chapters 4, 6, 7, and 8. Written comments can be sent to BOP@wyo.gov or mailed to the Board office at 1712 Carey Ave, Suite 200, Cheyenne, WY 82002 until 5 PM on March 28, 2017. In-person comments will be received on March 29, 2017, beginning at 10 AM at 2211 King Blvd, Casper, WY, in the hearing room of the Oil and Gas Conservation Commission. Copies of the proposed revisions are available from the Board office or at the Wyoming Secretary of State website at *https://rules.wyo.gov.*

Use of Store Sign-in/Login

By David Wills, MBA, WORx Manager

As Wyoming transitions into interstate data sharing of the WORx prescription drug monitoring program (PDMP) from one state to another, there are a few concerns that all pharmacy staff members need to remember. Pharmacy technicians and interns will soon register as delegates to provide WORx reports to the pharmacist, and "store sign-in accounts" should never be used. PDMPs want to know who is making the request as opposed to which pharmacy is making the request. The basic principle of the database is to identify patients with possible misuse or abuse problems. Because of the private health information, the security of the data must be maintained at all times. Multiple users of a single sign-in prevent identification of the pharmacist, pharmacy technician, or intern. For interstate data sharing, some PDMPs do not allow queries by pharmacy delegates (only the pharmacist).

I have spoken to two corporate executives, and the policies are clear. Use your own login information to access a state's PDMP patient information. Authorized users must register individually and not share their login or password information with anyone. The default username for the WORx database is your email address. Some pharmacists keep the login information on the back of their name tag, but it should not be posted where others might use it.

I have always recommended using a personal email address as your username rather than your employee email address. Stores close. Pharmacy staff move from time to time or change jobs and often forget about the WORx database. Trying to remember the password to every database is difficult. But if you use a personal email address as your username in WORx, you can always update your account through the "account settings" tab. If you need help changing any information, please call the Board office.

Wyoming to Become a Blueprint State

NABP has set up requirements for states to participate in the Blueprint Program for consistency of inspections of sterile compounding. Wyoming qualified for all five requirements by completing initial training for the inspectors, agreeing to ongoing training, inspecting no less than once every 18 months, sharing the inspection report through NABP, and using the universal inspection criteria form, beginning in 2017. The Board members approved participating in the program in December. Be prepared for longer inspections this year.

The *Wyoming State Board of Pharmacy News* is published by the Wyoming 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.

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