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News

Wyoming State Board of Pharmacy

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2014 Rules Revisions, Wyoming Pharmacy Act

Governor Matthew Mead signed two sets of rules revisions in 2014. The Wyoming State Board of Pharmacy members and staff reviewed all 17 chapters of rules and regulations under the Wyoming Pharmacy Act and all eight chapters under the Wyoming Controlled Substances Act. Spelling, grammar, numbering, and formatting were corrected throughout, and many other revisions were suggested and debated. A public comment period of 45 days was announced and a public hearing was held on November 5, 2013, in Casper, WY. Many comments were received. Three chapters were tabled until February 2014, and then the rulemaking notice went forward. A summary of revisions to the rules under the Wyoming Pharmacy Act are as follows:

Chapter 1, Board Practice, has updated procedures for complaints, investigations, and hearings.

Chapter 2, General Practice, has updated definitions, including for medication therapy management, which now includes Clinical Laboratory Improvement Amendments-waived testing. Wyoming will accept reciprocity from pharmacists licensed in California after January 1, 2004. Access to the Board's website will suffice rather than binders for *Newsletters* or the "Orange Book." Three feet is the minimum separation between patients at a pharmacy window. Notifications are now required for changes in ownership (21 days), changes in pharmacist-in-charge (PIC) (seven days), changes in a pharmacy address (30 days), and change in employment or address (15 days). A PIC can be absent from a pharmacy for up to 30 days for illness, vacation, etc, without requiring a change in PIC. Shipments are to be checked for contamination or counterfeiting, and items are to be quarantined for recalls. If a pharmacist is not on site at a retail pharmacy, a sign is to be posted. Interns may transfer non-controlled substance prescriptions out and in if a pharmacist is on the other end of the transaction. A pharmacy technician (but not a technician-in-training) may transfer non-controlled prescriptions out to a pharmacist. The prescription label shall include the purpose for use, where appropriate. Changes to the requirements for emergency drug boxes in long-term care are listed in Section 25. Under collaborative practice, a pharmacist can now make agreements with practitioners other than physicians.

Chapter 3 clarifies definitions and intern hour requirements. Chapter 4 updates the Code of Ethics. Chapter 5, Poisons, was repealed in 2011. The chapter 6 title was changed to Continuing Professional Education and clarifies auditing of earned hours using the National Association of Boards of Pharmacy® CPE Monitor® program.

Chapter 7, Computers, was repealed in 2011. Chapter 8, Manufacturers and Distributors, was reviewed but not revised. Chapter 9, Counseling and DUR, has updated language, and duplicate requirements were eliminated.

Chapter 10, Technicians, was a hot topic, and the final version was tabled until February 2014. The sections have been rearranged and the "grace period" for license renewal has been changed to 10 days following notification. The ratio of pharmacy technicians and/or technicians-in-training to pharmacists remains at 3:1, not counting enrollees in an American Society of Health-System Pharmacists-accredited training program during required experiential training hours.

Chapter 11, Dangerous Drugs, was **repealed.** Chapter 12, Institutional Practice, has several revisions, including how to destroy used transdermal controlled substance (CS) patches. Chapter 13 has a new title, Non-Sterile Compounding, and adds a Master Compounding Record requirement. Chapter 14, Telepharmacy, was not revised. Chapter 15, Long Term Care, clarifies the roles of the provider pharmacy and consultant pharmacist.

Chapter 16, Immunizations, was extensively revised due to changes in the statute, and articles appeared in previous *Newsletters*. Pharmacists can administer influenza vaccine to minors aged seven to 17 and to adults 18 years and over, as listed. Private space is described and must be in place by July 20, 2014. All administered vaccines must be reported to the state registry. Chapter 17, Sterile Compounding, was not revised.

All current rules and statutes are posted on the Board website at *http://pharmacyboard.state.wy.us.*

New Licensing Software

The Wyoming Board staff has been busy implementing new licensing software. Due to this change, some of the license numbers will appear differently. New pharmacy intern licenses will begin with "N," for example, N4213. Pharmacy technician-in-training permits will begin with "TT," for example, TT2356, and pharmacy technician licenses will begin with "T," for example, T2267. The records in the new system are more complete, and online renewals in November-December 2014 will be using the new procedure. License verification on the Board's website is improved; see "Search Database" and enter information in at least one field, such as a license number or last name.

New USP Webpage Answers Common Questions About USP Chapters <795> and <797>

In response to questions concerning United States Pharmacopeia-National Formulary (USP-NF) General Chapters <795> and <797>, USP has created a new frequently asked questions (FAQs) page on its website. The FAQs answer questions related to the Revision Bulletin for Chapter <795> that was issued on November 22, 2013, and became official on January 1, 2014. Among other topics, the FAQs address common questions regarding beyond-use dating and the differences between testing stability with strength (potency) or stability-inducing methods. The FAQs can be accessed at *www.usp.org/support-home/frequently-asked-questions/compounding*. Question four on the page includes a link to a USP article, "Strength and Stability Testing for Compounded Preparations."

Only You Can Prevent Look-Alike Sound-Alike Drug Names

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 Error Reporting Program. Report online at* www.ismp.org. *E-mail: ismpinfo@ismp.org.*

VESIcare/Vesanoid Mix-Up. A prescriber's office sent an electronic prescription to the patient's pharmacy; the prescriber intended to prescribe **VESIcare®** (solifenacin succinate) for overactive bladder but inadvertently selected **Vesanoid®** (tretinoin), which is used to induce remission of acute promyelocytic leukemia. The pharmacy technician entered the prescription for generic tretinoin; however, the pharmacy was unable to dispense the medication as the patient's pharmacy benefit manager required a prior authorization. The technician faxed a request and the prescriber's office replied back that VESIcare was intended. Both of these products are available in 10 mg solid oral dosage forms, increasing the risk of confusion. Investigate strategies (eg, tall man letters) to differentiate these products on computer screens. Prescribers should include the indication for the drug with the prescription. As always, providing patient education, especially for new prescriptions, is a good strategy to intercept errors before they impact the patient.

Benazepril Confused With Benadryl. A pharmacist reported a mix-up between benazepril **(Lotensin®)** and **Benadryl®** (diphenhydramine). A patient faxed a request to the pharmacy to ask for her "benazapryl." The pharmacist who received the fax interpreted it as Benadryl and placed a bottle of diphenhydramine in the bag for pick-up. Around this same time, the pharmacy went through a change in wholesaler and many manufacturers of generic products were changed. A few days later, a coworker of the patient picked up the medication (along with several others). The technician at the point-of-sale told the coworker that many of the manufacturers had changed recently and that some of the pills may look different. The patient received the diphenhydramine, filled her medication box with the capsules, and took diphenhydramine daily for three weeks before noticing she was unusually tired. When she brought the bottle back to the pharmacy, the error was recognized.

ISMP continues to receive reports of confused drug name pairs being involved in errors. ISMP wants to inform its readers of these drug name confusions so they may continue evaluating what measures they have in place to protect against these possible confusions.

Your Help Is Needed With Product Safety Testing. If you are a pharmacist, nurse, pharmacy technician, or other health care practitioner who is interested in furthering medication safety and error prevention, you can make a difference! Med-ERRS (a subsidiary of ISMP) is looking for assistance to help evaluate medication labels, drug packaging, and proposed drug names prior to submission by pharmaceutical and biotech companies for approval by Food and Drug Administration (FDA). The process is fun, simple, and easy. A small honorarium is paid. For more information or to sign up, visit *www.med-errs.com* and click on "Become a Reviewer."

FDA Issues Alert on Acetaminophen Products

In light of all the recent news alerts and warnings about the use of acetaminophen and acetaminophen-containing products, FDA issued a recommendation of importance to pharmacists, prescribers, and patients.

FDA recommends that health care providers consider prescribing combination drug products that contain 325 mg or less of acetaminophen. FDA also recommends that when a pharmacist receives a prescription for a combination product with more than 325 mg of acetaminophen per dosage unit that he or she contacts the prescriber to discuss a product with a lower dose of acetaminophen. A two-tablet or two-capsule dose may still be prescribed, if appropriate. In that case, the total dose of acetaminophen would be 650 mg (the amount in two 325 mg dosage units). When making individual dosing determinations, health care providers should always consider the amounts of both the acetaminophen and the opioid components in the prescription combination drug product.

FDA, in its MedWatch Safety Alert, reports that, "There are no available data to show that taking more than 325 mg of acetaminophen per dosage unit provides additional benefit that outweighs the added risks for liver injury. Further, limiting the amount of acetaminophen per dosage unit will reduce the risk of severe liver injury from inadvertent acetaminophen overdose, which can lead to liver failure, liver transplant, and death."

In January 2011, FDA asked manufacturers of prescription combination drug products containing acetaminophen to limit the amount of acetaminophen to no more than 325 mg in each tablet or capsule by January 14, 2014. FDA requested this action to protect consumers from the risk of severe liver damage that

can result from taking too much acetaminophen. More than half of manufacturers have voluntarily complied with FDA's request. However, some prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit remain available. In the near future, FDA intends to institute proceedings to withdraw approval of prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit that remain on the market.

Boards of pharmacy have received inquiries from pharmacists about remaining stock of the higher dose acetaminophen and what procedures should be followed. The FDA recommendation notes that pharmacists are advised to contact prescribers and request a change in the prescription. If the prescriber is not willing to make the change in the prescription, unfortunately, there is no clear cut recommendation at this point as to whether to dispense the higher dose acetaminophen product. It would appear that the higher dose acetaminophen-containing products will be regarded by FDA as unapproved and delisted from FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations,* commonly known as the "Orange Book." Until this occurs, pharmacists must make a judgment regarding continuing to dispense the higher dose acetaminophen containing products in light of the FDA recommendation and concern for patient safety.

Some Rohto Eye Drops Products Recalled

The Mentholatum Company of Orchard Park, NY, has issued a voluntary recall of some Rohto® eye drop products due to a manufacturing review at the production facility in Vietnam involving sterility controls. The recall has been issued at the retail level and includes Rohto Arctic, Rohto Ice, Rohto Hydra, Rohto Relief, and Rohto Cool eye drops that were manufactured in Vietnam. Products made in other facilities are not affected by the recall. To date, there has been no evidence indicating the recalled products do not meet specifications, according to a press release.

The recalled products are sold over the counter at pharmacies and retail stores throughout the United States, and can be identified by the words "Made in Vietnam" on the side carton panel under the company name and address information as well as on the back label of the bottle. Lot numbers for the recalled products contain the letter "V." Distributors and retailers are being notified by letter to stop distributing the products and to follow the recall instructions provided by the company. Questions about the recall can be directed to The Mentholatum Company at 877/636-2677, Monday through Friday, 9 AM to 5 PM Eastern Time. FDA urges consumers and health care providers to report any adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information and Adverse Event Reporting Program. More information is available at *www.fda.gov/Safety/Recalls/ucm382076.htm.*

FDA Provides Compounding Law Implementation Information

FDA has provided implementation information on Title I of the recently passed Drug Quality and Security Act – known as the Compounding Quality Act – through its website.

Of note, FDA specifies that compounding entities may register as an outsourcing facility, which, under certain conditions, may be exempt from the Federal Food, Drug, and Cosmetic Act's (FD&C Act) approval and labeling requirements. Drugs produced by compounders that are not registered as outsourcing facilities must meet the conditions of Section 503A of the FD&C Act, which was amended by the new law, to qualify for certain exemptions.

The document adds, "If a compounded drug does not qualify for exemptions under either section 503A or 503B of the [FD&C Act], the compounded drug would be subject to all of the requirements of the [FD&C Act] that are applicable to drugs made by conventional manufacturers, including the new drug approval and adequate directions for use requirements." FDA also notes it will provide additional information about how the agency will interpret certain provisions of Section 503A at a later date.

The implementation information may be viewed at *www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm375804.htm.*

New e-LTP Fees Effective July 1, 2014

Supporting ongoing efforts to protect the integrity of its licensure transfer programs and to support the expansion of new technologies that are being implemented to enhance the program, the National Association of Boards of Pharmacy® (NABP®) is adjusting the fees for the Electronic Licensure Transfer Program® (e-LTP™).

Beginning July 1, 2014, the e-LTP fees will be adjusted as follows:

- The preliminary application and first state transfer fee will increase from $350 to $375
- Each additional state transfer will increase from $50 to $75
- Change of states will increase from $50 to $75
- Time extensions will increase from $50 to $75

The fees for e-LTP were last adjusted in 2010. More information about e-LTP is available in the Programs section of the NABP website at *www.nabp.net.* Additional questions about the fee adjustment may be directed to Neal Watson, licensure programs manager, at 847/391-4406, or at nwatson@nabp.net.

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2014 Rules Revisions, Wyoming Controlled Substances Act

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Several housekeeping adjustments were made throughout the act, including spelling, numbering, and formatting corrections, as well as the deletion of outdated definitions and wording in Chapter 1. Chapter 2, Hearings, was updated to outline the procedures for complaints and hearings. Changes to Chapter 3, Fees for Registration and Re-registration, were minimal. Chapter 4 was not revised. Chapter 5, formerly Rules of Practice and Procedure, has been repealed because the process for contested case hearings is now listed in Chapter 2.

Several important changes have been made to Chapter 6, Issuing, Filing, and Filling of Prescriptions. The identification of patients has been moved from Chapter 2 to Section 7. Section 10 clarifies what a pharmacist can change on a Schedule II prescription. After approval from the prescribing practitioner, the pharmacist is permitted to change the drug strength, drug quantity, directions for use, and dosage form. The pharmacist is permitted to add or change the patient's address with proper verification without consulting the prescribing practitioner. The prescribing practitioner's Drug Enforcement Administration (DEA) registration number may be added to a prescription drug order after consulting the prescribing practitioner or verifying the number from another reliable source. Required information may appear on the front or back of the prescription drug order, and computer-generated data satisfies these requirements. Any change made by the pharmacist shall be documented and shall include the date, the name of person consulted, and the initials of the pharmacist. A pharmacist is **not** permitted to change the patient's name, CS prescribed (except for generic substitution permitted by state law), the date issued, or the prescriber's signature. Section 11 lists the process for multiple prescriptions for a 90-day supply of Schedule II CS. An individual practitioner may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a Schedule II CS provided the following conditions are met: each separate prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice; each individual prescription is dated with the date it was prescribed and contains all other information required by Chapter 6; the practitioner provides written instructions on each prescription indicating the earliest date on which a pharmacy may fill each prescription; and the practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse.

Notable changes were also made to Chapter 8, Prescription Drug Monitoring Program. These include updates to the process for registering and using the online program *(WORxPDMP.com)*. All faxed (paper) requests must include the DEA registration number for the pharmacy or practitioner. Pharmacists and practitioners may request patient profiles electronically provided the following conditions are met: the pharmacist or practitioner must first register for access to the online system using the online registration; the Board staff will activate the online access; and the Board staff shall discontinue access to any pharmacist or practitioner whose license, DEA registration, or Wyoming Controlled Substance Registration has lapsed, been revoked, or suspended.

Chapter 4, Records and Inventories, was not revised, as it was updated in 2011, and no further revisions are needed at this time. Chapter 7, Administrative Inspections, was reviewed by the Board and no revisions were made.

Recent Disciplinary Actions

E.K.G. Pharmacist #2569: License suspended for six months then conditioned due to dispensing from unsigned Schedule II prescriptions, unauthorized access to the pharmacy, adulterated products.

Nonresident Pharmacy License #06-80401: Administrative penalty of $7,500 for providing pharmaceuticals including CS without a proper emergency drug permit since 2007. Required to submit a plan to prevent future violations.

L.V. Pharmacy Technician License #1828T: Order of default to revoke license due to conviction of larceny from employer and failure to appear at a Board hearing.

Schedule of Board Meetings for 2014

- **June 25-26, 2014, Hilton Garden Inn, Casper (Meeting begins at 1 PM on June 25)**
- **September 10-11, 2014, The Inn at Lander, Lander, WY (Meeting begins at 1 PM on September 10)**
- **December 3-4, 2014, Casper**

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