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Montana Board of Pharmacy News

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Board Appointment Openings

The Montana Board of Pharmacy has two pharmacist positions open for appointment in July 2014. Interested pharmacists need to submit an application and a cover letter indicating why they are interested in serving on the Board. Board members are appointed by the governor, serve a five-year term, and may not serve more than two consecutive terms. A list of current Board members and their terms is available by visiting *http://boards.mt.gov* and then clicking on "Pharmacy, Board of" in the drop-down menu. Additional information for the online application and nomination process is available at *https://app.mt.gov/governor/*.

License Renewals and Continuing Education

Personal licenses for pharmacists, certified pharmacy technicians, and dangerous drug researchers must be renewed by July 1, 2014. All licensees should have received a reminder in the mail. To renew online, visit the Board's web page at *www.pharmacy.mt.gov* and click on "License Info," or go directly to *https://ebiz.mt.gov/pol* and click on "Health Care Licensing." As a reminder, all pharmacists seeking to renew their license must complete a minimum of 15 hours of continuing education (CE) each fiscal year. The fiscal year is July 1 to the following June 30. The 15 hours must include at least five hours of group or live CE. As an alternative to the live portion of the requirement, a pharmacist may complete a total of 20 hours of CE. Certified pharmacy technicians must comply with their certification board's CE requirements.

Marcie Bough Receives 2013 FDA Commissioner's Special Citation Award

Marcie Bough, PharmD, executive director for the Board, has been awarded the 2013 United States Food and Drug Administration (FDA) Commissioner's Special Citation Award from Commissioner Margaret Hamburg, MD. She was honored for her outstanding leadership, dedication to the advancement of the pharmacy profession, and support of FDA's mission to protect and to promote the public health.

In congratulating Marcie, Commissioner Hamburg recognized her as being a tremendous asset and an outstanding leader in her role developing and communicating the position of the American Pharmacists Association (APhA) on regulations and other FDA activities that affect pharmacists. Marcie worked for APhA in Washington, DC from 2004 to 2013.

Marcie was recognized for being called upon by the agency to speak at public hearings and for being instrumental in providing FDA opportunities to share important information with APhA membership. Her contributions related to FDA's implementation of Risk Evaluation and Mitigation Strategies were considered particularly noteworthy. Marcie was nominated for the award by her colleagues at FDA. The Board recognized her receipt of the award during the April 11, 2014 meeting.

Compliance Corner: 'Pharmacist-In-Charge' Reminders

Montana Administrative Rule 24.174.301(28) states in definition, "'Pharmacist-in-charge' [PIC] means a pharmacist licensed in Montana who accepts the responsibility for the operation of a pharmacy in conformance with all laws and rules [state and federal] pertinent to the practice of pharmacy, who assures that the pharmacy and all pharmacy personnel working in the pharmacy have current and appropriate licensure and certification, and who is personally in full and actual charge of such pharmacy. . ." In other words, as the PIC of a facility, you become responsible for all actions and activities in your facility.

Maybe you are the owner PIC or you have been asked to be the non-owner PIC. What does this mean to the Board, to Bob and Bill as inspectors for the Board, and more importantly, to you, the PIC? By now, most of you have been inspected multiple times in your facility and hopefully you are on the same page as the Board and its inspectors. However, the Board continues to see certain issues that you are responsible for that have somehow been missed in some locations. With this in mind, the Board felt that it was time for a PIC reminder related to what the Board will continue to review and look for on each site visit/inspection. Some things to consider:

- Is your facility license, all of its endorsements, and its Drug Enforcement Administration (DEA) license current and posted?
- Is the license and certification of each employee current and posted in your facility (this includes pharmacists, interns, technicians, and technicians-in-training)?
- Does each technician you employ have his or her certificate for being a certified pharmacy technician and his or her CE file up-to-date and on site?
- Is the DEA initial controlled substance inventory or biennial inventory current and on site?
- Is the technician utilization plan (if you use technicians) up-to-date, on site, and accessible?
- Are your policies and procedures for the facility and its employees current and in line with the practice standards of pharmacy?
- Are your collaborative practice agreements current, signed, and on site?
- Are all of your record keeping requirements current and available for inspection (prescriptions, profiles, invoices, inventories, etc)?
- Are you and your facility Health Insurance Portability and Accountability Act-compliant?
- Is your drug inventory properly stored and secured?
- Is access to the facility properly defined?
- Is patient consultation taking place in an appropriate area in the facility?
- Are you using any ancillary personnel to aid your facility and are they properly identified?
- Do you have Internet access to use the Board's web page (*www.pharmacy.mt.gov*) and the Montana Prescription Drug Registry (MPDR) program (*www.mpdr.mt.gov*)?

The Board recognizes this is a long list, but know that it is just the beginning of the inspection process you are responsible for in your facility as the PIC.

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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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In addition to all of the record keeping requirements, as the PIC you also are responsible for all the actions of personnel working in the pharmacy. So, how does a PIC stay on top of all of this, especially in a busy facility? Some recommendations include that you need to be properly trained as a PIC so that you can proactively train your staff, and then take time to revisit any problem areas.

As all of you know, things are changing rapidly in the practice of pharmacy and the facilities you work in. Communication is a key component in getting all the staff on the same page to meet all of these expectations. Whether you use policies and procedures, bring up files, automatic reminders, read-and-signs, e-mails, staff meetings, or some other avenue to get the information out to all your staff, it needs to happen. Issues need to be addressed sooner rather than later, as they will not go away on their own. The Board also suggests you actively use the Board website at *www.pharmacy.mt.gov* to stay up-to-date on issues, rules and regulations, *Newsletters,* and other important information from the Board. No one said it would be easy, but it is expected!

MPDR Update

Statistics: As of April 30, 2014, the MPDR had over 4.8 million prescriptions in its database, representing over 620,000 patients. Two thousand two hundred ninety-six users were registered, which is 24.4% of all eligible health care providers. Thirty-six and three-tenths percent of eligible health care providers who are located in Montana are registered to use the MPDR, and 55.4% of in-state pharmacists have registered. Over 21,800 patient history searches were conducted during the first quarter of 2014, bringing the total number of searches since the database's inception to over 121,000. During the first quarter of 2014, MPDR staff responded to 42 law enforcement subpoenas (239 since 2012) and three requests from licensing Board investigators (17 since 2012).

Fee Collection: This year's invoice for your $15 controlled substance fee (MPDR fee) was mailed on May 30, and your payments will be due by June 30. Watch your mail for an envelope from the Montana Department of Labor and Industry. Also, the MPDR home page *(www.mpdr.mt.gov)* will have a link to the online payment portal.

Education: MPDR staff presentations during 2014 have included the Montana Narcotics Officers Association, the Montana Nurses Association, the Montana Pharmacy Association's (MPA) 2014 Spring Seminar in Billings, MT, and the Montana Coroners Association. Future presentations include three health care professional associations and the Montana Crime Prevention Conference. MPDR staff had a display table at the January meeting of the MPA where they were able to connect with attendees and answer their questions. MPDR staff also had a display table at April's Prescription for Prevention Summit in Missoula, MT. Please contact MPDR staff at 406/841-2240 if you would like them to schedule a training session for providers in your area.

System Enhancements: MPDR staff and their software vendor, Montana Interactive, are hard at work on Phase 2 modifications to the MPDR's online service. MPDR staff is putting the finishing touches on a pharmacy compliance audit report that will enable MPDR staff to identify pharmacies that are not meeting reporting requirements. MPDR staff hopes to have the new audit procedures in place within the next few months.

The next projects are focused on planning, analyzing, and designing system features that will allow authorized providers to delegate MPDR access to approved members of their health care team. The pharmacist or prescriber will be responsible for online delegate authorization and for monitoring the MPDR searches a delegate conducts on his or her behalf. This complicated enhancement project involves the creation of an online registration service for delegate accounts, creation of management capabilities for supervising providers and MPDR staff, and modifications to the online search service.

Once delegate accounts are available online, the next project will be to focus on an interstate data-sharing enhancement so that MPDR can share and receive data with drug registries in other states. Stay tuned to future *Newsletters* for more information about the MPDR's system enhancements. For more information on the MPDR program, visit *www.mpdr.mt.gov*.

Marinol (Dronabinol) Is Schedule II in Montana

Please be advised that Marinol® (dronabinol) is Schedule II in Montana, not Schedule III as scheduled by DEA. Pursuant to Montana Code Annotated (MCA) §50-32-224, Specific dangerous drugs included in Schedule II, dronabinol (synthetic) is listed under hallucinogenic substances, 50-32-224(5)(a), MCA. Prescription orders and corresponding requirements for this product should be managed as Schedule II prescriptions, as Montana law is more restrictive.

Board Reminders

***Newsletter* Mailings and E-Mailing:** The *Montana Board of Pharmacy Newsletter* is mailed to all pharmacies and facilities within the state in addition to out-of-state mail-order pharmacies. The *Newsletter* will continue to be e-mailed to those who have signed up through the National Association of Boards of Pharmacy® (NABP®). To sign up, send an e-mail to MontanaBoPNewsletter@nabp.net and type "Subscribe" in the subject heading.

***Newsletters* Online:** The *Newsletter* issues from 2009 to present are available on the Board's website at *www.pharmacy.mt.gov* (click on "Board Info" and then on "Newsletters"), and through NABP's website at *www.nabp.net/publications/state-newsletters*.

Meeting Dates: The next Board meetings will be held in Helena, MT, on July 11, 2014, and October 10, 2014.

The *Montana Board of Pharmacy News* is published by the Montana 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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