January 2014

Montana Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

PO Box 200513 • 301 S Park Ave, 4th Floor • Helena, MT 59620-0513

Board Member Appointments

In October 2013, two Montana Board of Pharmacy appointments were confirmed by Governor Steve Bullock. Rebekah Matovich, CPhT, was appointed for a second term as the certified pharmacy technician (CPhT) member. Rebekah works at and co-owns the Columbus Health Mart Pharmacy in Columbus, MT. Charmell Petroff Owens was appointed as the new public member and replaces outgoing public member Frances Carlson. Charmell is the program director for the Ravalli County Drug Free Communities Program and the Ravalli County Prevention Coalition in Hamilton, MT. The Board looks forward to the contribution these members will provide. Both terms will expire July 1, 2018. Thank you to Frances for her hard work and dedication to the Board.

News from the Montana Prescription Drug Registry

Donna Peterson, MPDR Program Manager

I am pleased to announce that the Montana Prescription Drug Registry (MPDR) program recently won a 2013 Digital Government Achievement Award for Excellence in Government to Citizen Services. This prestigious award is the online equivalent of the Oscars, and we are very proud to have won an Honorable Mention for cutting-edge Web development. MPDR staff and the Board are committed to providing you with the same level of excellence with each of our future system enhancements for the program.

In addition, the MPDR received a new grant through the Montana Board of Crime Control from the federal Department of Justice, Bureau of Justice Assistance. This grant will enable us to continue expanding the services and program enhancements offered by the MPDR through early 2015.

MPDR Statistics as of November 30, 2013:

- Pharmacies reporting to the MPDR: 749
- Prescriptions currently in the database: Over 3.9 million
- Patient prescription history timeline: July 1, 2011 to present (eventually a three-year history)
- Patients represented in the database: Over 555,000 (some are duplicates)
- Total eligible providers to search patient history: 9,229
- Total registered providers to search patient history: 1,904 (21.1%)
- Registered users by license type (% of eligible): pharmacists: 33.5%; physicians: 14.3%; naturopathic physicians: 6.3%; resident physicians: 3.4%; physician assistants: 36.8%; advanced practice registered nurses: 35.2%; dentists: 20%; optometrists: 4.0%; and podiatrists: 7.9%

New MPDR Feature: The MPDR's information page, *www.mpdrinfo.mt.gov*, now includes a detailed, illustrated guidance document for pharmacy staff/vendors. This guide covers basic features like registration, logging in, and submitting data to the registry, as well as features such as monitoring your data submissions and updating your contact information. **This is a great resource tool for new and experienced MPDR users.**

MPDR Data Submission: As a reminder, the pharmacist-in-charge is responsible for ensuring that the pharmacy's MPDR reporting requirements are met – even if the pharmacy relies on a third-party software vendor or corporate office to submit weekly MPDR reports. If reporting requirements are not met, and if data submission errors are not corrected and resubmitted, data is missing from the MPDR and the pharmacy may be considered out of compliance. MPDR reporting requirements include:

- Every Montana-licensed pharmacy (except a wholesale drug distributor or an institutional pharmacy) is required to submit weekly reports to the MPDR, whether or not any controlled substances were dispensed during the previous week.
- If an error message results from the submission, **the pharmacy is required to correct that data in the system and then resubmit the corrected data to the MPDR within eight days** of the original date of submission.

If you have questions, please contact your vendor or call MPDR staff at 406/841-2240.

MPDR Online Resources: The "How Do I" and "Instructions" links at the top of the MPDR Web pages give detailed, step-by-step instructions on using the MPDR. The MPDR's home page, *www.mpdr.mt.gov*, is the starting point for all MPDR-related activities, including registration to access the registry, logging in to submit prescription data, and logging in to search patient histories. Follow the links provided on the Web page. The MPDR's information page, *www.mpdrinfo.mt.gov*, contains the pharmacy guidance document, additional information about the MPDR, and a variety of links related to prescription drug abuse, provider screening tools, education, and community resources.

Pharmacy Technician Checklist to Obtain and Maintain Licensure

Bob Stenberg, Compliance Specialist and Board Inspector

There seems to be some confusion with what needs to happen for a person to become and maintain licensure as a CPhT in Montana. There are multiple steps to consider for licensure as a CPhT or starting with the pharmacy technician-in-training (TTR) process. This checklist should be helpful to applicants and pharmacy managers.

When an application for either license is submitted, the following apply:

- A complete and routine application may take up to 30 days to be processed and considered by Board staff for licensure.
- The applicant will be notified if the application is incomplete, if additional information is required, or if the application is considered non-routine and needs to be reviewed by the Board at a regularly scheduled Board meeting.
- Non-routine applications may take up to 120 days to process.

continued on page 4

Changes to Fentanyl Pain Patch Warnings Required by FDA

To reduce the risk of accidental exposure, Food and Drug Administration (FDA) has announced new requirements that change the appearance of fentanyl pain patch warnings to make them more visible. The change also requires new language in the warning that emphasizes the risk of death from accidental exposure, particularly in children. The announcement coincided with a Consumer Update that stressed the potential danger of improperly discarded fentanyl patches to children and pets. FDA reminded consumers of the agency's previous advice for securely storing unused patches and disposing of used fentanyl patches by folding the sticky sides together and then flushing them down the toilet. The agency also advises patients to cover in-use patches with an adhesive film to keep them from coming loose, and to regularly check patches to ensure they are securely in place. FDA offers additional information for health care providers on the "Fentanyl Transdermal System (marketed as Duragesic) Information" page, available at *www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm114961.htm*. Consumer information about safe drug disposal methods is also available on the AWAR$_X$E® Web site at *www.AWARERX.ORG*.

New: Free ISMP Medication Safety Alert! Newsletter for LTC Facilities

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 is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also an FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at* www.ismp.org. *ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

In July, ISMP began publishing *Long-Term Care Advise-ERR,* a new *ISMP Medication Safety Alert!* newsletter for nurses and administrators in long-term care (LTC) facilities. ISMP receives error reports that have occurred in LTC facilities. The newsletter is provided free to LTC facilities in the United States thanks in part to corporate sponsorship from Lilly and for a nominal subscription fee for pharmacies that service LTC facilities and others. Please visit ISMP's Web site at *www.ismp.org/Newsletters/longtermcare* for more information, and let your LTC facilities know about this free offer.

Here are a few excerpts from a recent issue.

Immediate Vs Extended Release Error

A physician called a LTC facility to change a resident's oxycodone order from an extended-release formulation to an immediate release formulation at the same dose and frequency. The nurse receiving the verbal order transcribed it as "Discontinue OxyContin 10 mg BID, Start OxyContin 10 mg IR BID," with "IR" meant to represent immediate release. Although Oxy**Contin**® is a brand of oxy**codone,** it is only available as an extended-release tablet. The pharmacy had previously been dispensing Oxy**Contin** for the resident, so the nurse thought she could communicate the prescriber's order by discontinuing the current Oxy**Contin** order and then ordering Oxy**Contin** as an immediate-release product. The pharmacy continued dispensing Oxy**Contin.** The differences between these products and formulations were brought to the attention of nursing staff via an in-service. To minimize the risk of confusion, do not attach modifiers such as "IR" for immediate-release or "RS" for regular strength unless it is part of the official drug name.

Errors Occur During Transitions of Care

A pharmacist reported the following hazardous situation that can occur during a hospital to LTC transfer. Residents are often admitted to a LTC facility with a list of medications printed from the hospital pharmacy computer. On these printouts, doses are expressed along with the number of tablets. For example, the printout may list hydrochlorothiazide 50 mg/2 tablets daily for an order in which the total dose was 50 mg because the hospital only stocks the 25 mg tablets. During hospitalization the patient required two tablets for each dose; however, the LTC nurse may misinterpret the order to mean two 50 mg tablets, making the total dose 100 mg, or two times more than prescribed. This issue arises every time the resident's total dose in the hospital requires more than one tablet or capsule. Discharge medication summaries and transfer orders should only list the total dose in mg or mcg and other directions for use (ie, frequency, route, drug name) to avoid misinterpretation.

2013 USP Chapter <797> Compliance Survey Shows Compliance Trends Unchanged From 2012

The 2013 United States Pharmacopoeia (USP) Chapter <797> Compliance Survey, the third annual report released since 2011, shows that the overall compliance rate of 77.2% remains nearly unchanged from the 2012 rate. Budgetary restrictions and physical plant limitations were among the top challenges to compliance by survey respondents. The report also details the

survey's findings on what types of facilities are participating in compounding, and compliance in specific domain areas such as environmental sampling and gloved fingertip sampling. Of the survey's 1,045 participants, 97% of the survey's respondents said that USP Chapter <797> "has had a positive influence on patient safety." The report notes National Association of Boards of Pharmacy® (NABP®) efforts to assist state boards of pharmacy in evaluating pharmacy compliance with USP Chapter <797> requirements for sterile compounding in their states. The report also noted that those who participated in the 2011 survey had a higher compliance score than those who did not. The survey's authors encouraged pharmacy owners with multiple areas of noncompliance to target one or two areas to improve. They also encouraged organizations that participated in the survey to make use of the free Action Plan – generated upon completion of the survey – and other free resources to "reshape" their sterile compounding practices. The full report on the survey's results is available in the October 2013 issue of *Pharmacy Purchasing & Products Magazine* and on the magazine's Web site at *www.pppmag.com/article/1403*.

FDA Recommends Schedule II Classification for Hydrocodone Combination Products

FDA planned to submit a formal recommendation to reclassify hydrocodone combination products as Schedule II controlled substances to the Department of Health and Human Services by early December 2013. FDA expects the National Institute on Drug Abuse to concur with the recommendation, indicates a statement on the FDA Web site. FDA also indicates that while "the value of and access to these drugs has been a consistent source of public debate," the agency has "been challenged with determining how to balance the need to ensure continued access to those patients who rely on continuous pain relief while addressing the ongoing concerns about abuse and misuse." Drug Enforcement Administration makes the final decision about the appropriate scheduling of these drugs. In January 2013, FDA's Drug Safety and Risk Management Advisory Committee made a recommendation that hydrocodone combination products be classified as Schedule II drugs following a 19-to-10 vote that concluded a two-day meeting during which members discussed the potential for abuse and misuse of the medications and the potential impact of rescheduling the drug products. FDA's statement on the recommendation is available at *www.fda.gov/Drugs/DrugSafety/ucm372089.htm*.

New FDA Drug Info Rounds Training Videos Available

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better medication decisions. In the latest two Drug Info Rounds videos, pharmacists discuss the review and approval of new drug names and the review of marketing and advertising materials for new drugs. The videos can be viewed at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm368620.htm* and *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm371785.htm,* respectively. Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, and Division of Drug Information.

CPPA Developing Specialty Pharmacy Accreditation Program

The Center for Pharmacy Practice Accreditation® (CPPA) has announced the development of a new accreditation program for specialty pharmacy practices. CPPA Executive Director Lynnae Mahaney, MBA, RPh, FASHP, VHA-CM, indicates that "CPPA will be able to develop the new specialty pharmacy standards quickly and efficiently with the existing standards development methodology, infrastructure, and network of specialty pharmacy expertise."

CPPA is a partnership between the American Pharmacists Association, the American Society of Health-System Pharmacists, and NABP. CPPA develops and implements comprehensive programs of pharmacy practice site accreditation, including the promotion, development, and maintenance of principles, policies, and standards. CPPA offers the general public and users of pharmacy services a means of identifying those pharmacies that satisfy the accreditation criteria and are focused on advancing patient care, safety, and quality.

More information may be found in the press release, available at *www.pharmacypracticeaccredit.org/news/2013/10/cppa-to-develop-specialty-pharmacy-accreditation-program*.

National Association of Boards of Pharmacy Foundation, Inc
1600 Feehanville Drive
Mount Prospect, IL 60056

MONTANA BOARD OF PHARMACY

Presorted Standard
U.S. Postage
PAID
Chicago, Illinois
Permit No. 5744

continued from page 1

- Applicant must be 18 years or older (submit proof of age with copy of driver's license, birth certificate, or other verification), and submit a copy of high school or equivalency certificate, photo, and payment.
- The application must list three character references (one must be a registered pharmacist). References should submit their completed form directly back to the Board, not the applicant, as soon as possible in order to complete the application. For TTR, reference forms are due before the end of the 18-month TTR license.
- An applicant who has already passed the CPhT exam and/or is licensed in another state as a CPhT does not need to submit a TTR application, just the technician application.

Keep the Board office informed at all times of any address changes, change in registration status, and/or complaints or disciplinary action from another Board.

When one starts this process, I recommend that the applicant start a file with a complete timeline on all steps documented with who, what, where, when, and why. For example, document speaking with pharmacist John Doe about character reference and that he said he would complete and mail the reference within two days. Also, if you talk with anyone at the Board office, document the discussion and include date, time, and who you spoke with. Also, document when an exam certificate is submitted.

Once a TTR license has been issued, the licensee has 18 months to pass the certification exam issued by the Pharmacy Technician Certification Board (PTCB), Exam for the Certification of Pharmacy Technicians (ExCPT), or other Board-approved certifying entity. I recommend that applicants not wait until the very end of the process to take the exam. The license to practice as a TTR is valid for a period of no longer than 18 months as stated by rule.

When the certification exam is passed, the TTR licensee or CPhT applicant needs to mail or fax a copy of the certificate to the Board in order to complete the necessary documents and issue the CPhT license provided all other requirements are met. It is very important to recognize that the certification entities do not contact the Board; an applicant/licensee must inform the Board directly by submitting a copy of the CPhT certificate.

Additional necessary steps for maintaining licensure include paying the annual Board renewal fee in June for the CPhT license and separately recertifying every two years with PTCB, ExCPT, or other approved entity that issues a technician's certification. Generally, this requires proof of 20 continuing education (CE) hours and a fee to the certifying entity. I recommend that technicians aim for one CE a month and keep a file of educational materials at their pharmacy of employment. To obtain credit for CE accredited by the Accreditation Council for Pharmacy Education (ACPE), technicians must provide a National Association of Boards of Pharmacy® (NABP®) e-Profile ID number and date of birth (MM/DD) to the CE provider. To obtain an e-Profile ID, technicians must create an NABP e-Profile and register for CPE Monitor®. This can be done by visiting *www.MyCPEmonitor.net.* A record of your completed ACPE-accredited CE will be transmitted automatically to your e-Profile through CPE Monitor once it is verified by ACPE. If a technician keeps track of CE credits with, for example, Pharmacy Technician's Letter, or another process, be aware that the technician, not the CE group, is responsible for submitting CE credits to the applicable certification entity.

If there is any change in your address, e-mail, or contact information, make sure that you notify both the Board and your national certification board.

The Board hopes that this helps clarify what is needed to achieve and maintain a technician license. Technicians should document and keep records in a retrievable file so if a question arises they know where to obtain information to answer that question. More information is available in the application forms at *www.pharmacy.mt.gov.* Click on "Forms" and then on "License Application Forms."

Board Reminders/Updates

- **Collaborative Practice Agreements:** For those participating in collaborative practice agreements, please know that the letter you are now receiving confirms receipt of your completed agreement for filing with the Board office, not approval of the agreement. In addition, the effective date indicated in your agreement determines the one-year expiration/renewal timeline rather than a date provided or determined by Board staff. For additional information on collaborative practice agreement requirements, please see Board Rule 24.174.524 ARM, or contact Marcie Bough, PharmD, executive director, at 406/841-2371.
- **Newsletter Mailings and e-Mailing:** Starting in 2014, the *Montana Board of Pharmacy Newsletter* will be 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 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 2008 to the current issue are available on the Board's Web page at *www.pharmacy.mt.gov* (click on Board Info then on Newsletters) and through NABP's Web page at *www.nabp.net/publications/state-newsletters*.
- **Meeting Dates:** The next Board meeting will be held on January 10, 2014, in Big Sky, MT, in conjunction with the Montana Pharmacy Association's Winter CE & Ski Meeting. Additional meetings include April 11, 2014, 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, Inc, 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 the Foundation or the Board unless expressly so stated.

Marcie Bough, PharmD - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Deborah Zak - Communications Manager