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Message from the New Executive Director

Marcie A. Bough, PharmD

To my fellow Montanans: It is great to be back home and I am thrilled to be serving as your new executive director for the Montana Board of Pharmacy. I started work April 22, 2013, and am settling into my role with the Department of Labor and Industry. I look forward to working with the Board members, pharmacy inspectors, licensing staff, and others at the department. Importantly, I also want to hear from and work with you – the licensees – on the regulatory issues that may need to be addressed and/or those that are working well as you provide care and services across the state. I will need your input to help ensure that we are moving forward together in a path that continues to support public safety and a strong pharmacy community. We also need to work in collaboration with other members of the health care team and their respective boards as the health care system continues to evolve.

As background, I am from Highwood, MT (near Great Falls, MT), and from 2004 to 2013, I worked for the American Pharmacists Association (APhA) in Washington, DC. I truly enjoyed my time with APhA, where I started on the practice team and in 2007 transitioned to policy work as director of federal regulatory affairs and then senior director of government affairs. I served as primary liaison and lobbyist to the federal regulatory agencies and led the association's efforts in developing and communicating APhA's positions on regulations, and in testifying and participating in agency and other stakeholder meetings. I spent the majority of my time working with Food and Drug Administration, Centers for Medicare and Medicaid Services, Drug Enforcement Administration (DEA), the White House Office of National Drug Control Policy, and serving as a resource on APhA's legislative activities. In addition, I collaborated with stakeholders in pharmacy, medicine, health information technology, and manufacturing, and led a group of 14 national pharmacy organizations working together on health care reform implementation and other legislative and regulatory issues important to pharmacy. I will draw on my federal experiences to help guide me in my work for the Board.

Prior to pharmacy school, I spent three years working for the United States Senate Committee on Indian Affairs, chaired by Senator Ben Nighthorse Campbell of Colorado. It was a great experience that helped direct my pharmacy career pathway. I received my bachelor of science degree in biomedical science from Montana State University in 1996, and my PharmD from the University of Montana in 2004. My twin sister, Mary Bough, works as a pharmacist in Bozeman, MT.

Finally, know that I am committed to working and collaborating with the Montana Pharmacy Association, the University of Montana Skaggs School of Pharmacy, the National Association of Boards of Pharmacy® (NABP®), and other stakeholders as we lead pharmacy policy, advocacy, licensing, and education efforts on behalf of the individuals in Montana. I look forward to working with you. You are welcome to contact me at mbough@mt.gov or at 406/841-2371.

2013 Legislative Session and Upcoming Regulatory Revisions

Several bills from the 2013 Montana Legislative Session were signed into law that will require the Board to pursue regulatory action to align with statutory language (expect to see draft rules for comment in the near future).

- **House Bill 140,** generally revising controlled substance (CS) laws, applies to ARM 24.174, Subchapter 14, Dangerous Drug Act, revises listed drugs CS I through V, and makes other revisions. Examples include the Schedule I listing of synthetic cannabinoids (ie, synthetic cannabis/marijuana) and substituted cathinones (ie, bath salts). This law is effective October 1, 2013.

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Pharmacists Likely to Recommend OTC Medications, CHPA Reports

Patients most often seek a pharmacist's advice on treating coughs, headaches, migraines, and allergies, and 98% of pharmacists recommend or have no reservations recommending over-the-counter (OTC) products to treat such ailments, according to a recent survey. The Consumer Healthcare Products Association's (CHPA) report, "Understanding Trust in OTC Medicines: Consumers and Healthcare Provider Perspectives," presents the results of the survey, which was developed to better understand what drives consumer and health care provider trust in OTC products. The survey, developed and conducted by Nielsen and IMS, included over 1,100 consumer respondents, and over 500 health care provider respondents, composed of pharmacists, pediatricians, nurse practitioners, and primary care providers.

Pharmacists surveyed reported that they were more likely to recommend OTC products that demonstrated successful patient outcomes and consistent outcomes, and products known to be as efficacious as a prescription drug, and those containing ingredients known to be safe.

The survey also asked health care providers whether they recommended OTC products without, before, or in conjunction with recommending prescription drugs for certain symptoms. A majority of pharmacists surveyed, over 60%, recommend OTC medications to treat stomach symptoms and pain, without recommending a prescription treatment, and over 70% recommended OTC allergy, sinus, and flu medications without advising that a prescription drug is needed.

CHPA notes that with the expansion of patient self-care, OTC products will play an increasingly important role in health care. The potential for more prescription products to become OTC products in the new paradigm under consideration by Food and Drug Administration (FDA) could further impact this trend. As consumers are becoming more empowered in making health care decisions, they are also relying more on their pharmacist for medication advice. In fact, Nielsen and IMS findings show that multigenerational households, Hispanic households, and households who care for an adult outside of their home place a high value on pharmacist recommendations regarding selecting appropriate OTC medications, notes CHPA.

The full CHPA White Paper is available at *www.yourhealthathand.org/images/uploads/OTC_Trust_Survey_White_Paper.pdf.*

ISMP Study on Targeted Mandatory Patient Counseling

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency 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 a recent study funded by a grant from Agency for Healthcare Research and Quality, ISMP evaluated the use of a combined checklist and patient information leaflet used during mandatory counseling sessions for consumers who pick up a filled prescription for 11 targeted medications:

- Opioid-containing analgesics
  - fentanyl patches
  - hydrocodone with acetaminophen
  - oxycodone with acetaminophen
- Anticoagulants
  - warfarin
  - enoxaparin
- Antidiabetic drugs (insulin analogs)
  - Humalog® (insulin lispro)
  - NovoLog® (insulin aspart)
  - Levemir® (insulin detemir)
  - Lantus® (insulin glargine)
  - Apidra® (insulin glulisine)
- Antineoplastic drug (non-oncologic use)
  - methotrexate

All 11 medications are on ISMP's list of high-alert medications dispensed from community pharmacies. Errors with high-alert medications may not be more frequent than errors with other medications; however, the consequences of errors with high-alert medications are often harmful. These 11 medications are also among the top 200 drugs dispensed in the United States, and many are used to treat chronic conditions, thus increasing the potential impact on public safety.

The medications were flagged in some manner to identify mandatory counseling opportunities. When a patient or patient representative picked up a flagged prescription, a pharmacist conducted a short counseling session (one to three minutes) that included the exchange of several key points on the checklist. At the end of the counseling session, the pharmacist provided the leaflet to the patient, along with a survey to complete and send back to ISMP.

Counseling sessions for these drugs were conducted for a consecutive period of four weeks, during which time, one trained ISMP staff member observed the counseling sessions for one day (six hours) to collect information on factors that facilitate or inhibit the counseling sessions. At the end of the four-week period of mandatory counseling, pharmacists at participating pharmacies were asked to complete a short mail-in survey regarding their perceived value of the process.

Results of the study showed that these consumer leaflets offer important safety tips for taking medication safely. Each leaflet begins with, "High-alert medicines have been proven to be safe and effective. But these medicines can cause serious injury if a mistake happens while taking them. This means that it is vitally important for you to know about this medicine and take it exactly as intended."

ISMP tested the readability, usability, and perceived value of the leaflets. Ninety-four percent of patients felt the leaflets provided great information or good information to know. Ninety-seven percent felt the information in the leaflets was provided in a way they could understand. Eighty-two percent of patients taking the drug for the first time and 48% of patients who had previously taken the medication reported learning something new. Overall, 85% of the patients felt they were less likely to make a mistake with the medication because they had read the leaflet.

The leaflets are available for download and can be reproduced for free distribution to consumers at *www.ismp.org/AHRQ/default.asp?link=ha.*

Generic Drug Substitution Requires Pharmacist Attention to State Laws and Regulations

While 40 years ago, most states forbade prescription drug substitution, almost all states now have drug product selection laws that allow, encourage, or mandate pharmacists to substitute generics for brand-name

drugs. These laws vary widely from state to state and pharmacists are therefore encouraged to review their state's substitution laws to ensure that they understand and comply with the state's requirements.

FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* publication, commonly known as the *Orange Book,* is generally considered the primary source for identifying suitable generic alternatives for a brand-name drug, and while not mandated by FDA regulations, the majority of states use the *Orange Book's* determinations of therapeutic equivalence to legally guide pharmacists in substituting generics.

State laws on generic substitution vary widely. A few states, such as Kentucky or Minnesota, follow a "negative formulary" approach, in which substitution is permitted for all drugs except those that appear on a particular list. Other states, including Massachusetts and Wisconsin, use a "positive formulary" approach, in which substitution is limited to the drugs on a particular list.

States also differ as to whether their substitution laws are permissive, thereby allowing a pharmacist to substitute a generic version of a brand-name drug, provided all prescription requirements are met, or mandatory, thereby requiring substitution. Prescription requirements may include such factors as the availability of a cheaper, therapeutically equivalent drug, the prescriber's specification that a brand-name drug be dispensed, or requiring the patient's or prescriber's consent. As reported in the 2013 NABP *Survey of Pharmacy Law*, 14 boards of pharmacy indicate that generic substitution falls into the "mandatory" category, while 38 boards indicate that their substitution laws are "permissive." Oklahoma law states that "[I]t is unlawful for a pharmacist to substitute without the authority of the prescriber or purchaser."

Other regulatory variations include states specifying the acceptable means for the prescriber to designate that substitution is not authorized, and states requiring patient consent prior to substitution.

The full article on this subject, which also reviews considerations regarding the accuracy of therapeutic equivalent determinations, is available in the June-July 2013 *NABP Newsletter,* which may be accessed in the Publications section of *www.nabp.net.*

NHF Provides Standards of Care for Pharmacies Serving Hemophilia Patients

For pharmacies that offer blood-clotting medications, organizations such as the National Hemophilia Foundation (NHF) emphasize the importance of being able to meet the specialized needs of their patients with bleeding disorders.

NHF's Medical and Scientific Advisory Council (MASAC) issued a standards-of-care recommendation in 2008 to assist pharmacies providing clotting factor concentrates for home use to patients with bleeding disorders. MASAC's guidelines are intended to be minimum standards of care and are divided into six areas:

As a brief overview of the MASAC guidelines, pharmacists wishing to meet the standards should:

1. Have a basic knowledge of bleeding disorders and experience with and knowledge of the full range of clotting factor concentrates, ancillary supplies, and hazardous waste disposal.

Pharmacies wishing to meet MASAC standards:

2. Should be able to provide a full range of available concentrates in all available assays and vial sizes, along with all necessary ancillary supplies, and hazardous waste disposal assistance as well as access to nursing services.
3. Should support reliable access to clotting factor for appropriate home treatment, by filling prescription orders within 48 hours, in the quantities prescribed, with expiration dates commensurate with the individual patient's needs.
4. Should be reliably open during regular business hours; provide 24-hour emergency access; and have an emergency action plan that allows patients to receive factor within 12 hours "in case of emergent need," with a goal of three hours "where logistically possible."
5. Should deliver products to the patient's desired location, meeting federal medication shipping standards, and providing an emergency number for patients to call in case of a problem with a delivery.
6. Should maintain patients' treatment prescription information along with maintaining records in compliance with state and federal requirements and be able to track the clotting factor products from manufacturer to patient, and participate in a recall information system.

The full article on this topic is available in the June-July 2013 *NABP Newsletter,* accessible in the Publications section of *www.nabp.net.* NABP notes that each state needs to review the standards recommended by MASAC to determine whether they coincide with existing state board of pharmacy requirements. NABP recognizes the unique patient needs of hemophiliacs, but also the responsibility of state boards of pharmacy to set required standards for medication dispensing and use. NABP is working with NHF to help the boards of pharmacy gain a better understanding of the medication needs of patients to help achieve uniformity in related regulations.

NABPLAW Online Now Includes Guam, Puerto Rico, and the Virgin Islands

The complete pharmacy acts and regulations of Guam, Puerto Rico, and the Virgin Islands are now included in **NABP***LAW*® Online, the comprehensive national data bank of state pharmacy laws and regulations provided by NABP. **NABP***LAW* Online's powerful search capabilities allow users to research subjects one state at a time or across all 50 states and included jurisdictions. More information about **NABP***LAW* Online and a link to the online subscription order form are available in the Programs section of the NABP Web site at *www.nabp.net/programs/member-services/nabplaw/.*

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- **Senate Bill 149,** revising collaborative practice laws for pharmacy immunizations, applies to ARM 24.174.503, Administering of Vaccines by Pharmacists. Revisions authorize immunization-certified pharmacists to prescribe and administer immunizations without a collaborative practice agreement in place for the following: influenza for those 12 years and older; pneumococcal polysaccharide vaccine, tetanus, and diphtheria to those 18 years and older; herpes zoster to those identified in Centers for Disease Control and Prevention guidelines; and in the event of an adverse reaction, epinephrine or diphenhydramine to those 12 years and older. This law is effective October 1, 2013.

Of interest, but not requiring pharmacy regulatory changes, is Senate Bill 165, authorizing emergency use of epinephrine in schools. The law specifically references that the school is the patient and that the prescription must be filled by a pharmacy. This law became effective July 1, 2013. The Board will be working with other stakeholders as efforts continue to raise awareness about this new law.

Coming soon for public comment will be a draft rule revising the Montana Prescription Drug Registry (MPDR) reporting requirements in addition to a larger draft rule package revising a variety of pharmacy regulatory provisions.

Proposed rules will be posted on the Board Web site at *www.pharmacy.mt.gov.*

Board Reminders

- **MPDR:** As of June 2013, over 1,600 users were registered to use the MPDR program, with over 28% of eligible pharmacists registered. The program has over 3.1 million prescriptions in the database. For program updates and information, go to *www.pharmacy.mt.gov* and click on the "Drug Registry" tab.
- **MPDR Error Reports and Missing Information:** If your pharmacy's CS dispensing information was submitted but does not appear in the MPDR database search results for a specific patient, check to see if the pharmacy received an **error report** e-mail message indicating that information was rejected due to incorrect file format and/or missing or invalid data fields. **Error reports** are generated when some or all of the information is not successfully uploaded into the registry's database. If your pharmacy works with a third-party vendor and/or corporate office to submit MPDR CS dispensing reports, be sure to check with them about receiving such error reports as the e-mail messages may not be coming directly to the pharmacy. The pharmacy registered with MPDR is responsible for ensuring that errors are addressed and that corrected reports are resubmitted to the registry. For additional reporting information, please see the technical specification resource online at *www.PDRRegistration.mt.gov* or contact MPDR at 406/841-2240.
- **Reporting Form 106:** If your pharmacy has theft or loss of CS, be sure to complete a DEA Form 106, submit it to DEA, and send a copy to the Board. Specific DEA information is available online at *www.deadiversion.usdoj.gov/21cfr_reports/theft/.* Contact the Board if you have questions about completing the form.
- **Renewals:** Pharmacist and pharmacy technician renewals ended on June 30, 2013, with the exception of late renewals. Your license should now read that it expires on June 30, 2014.
  - If you need to update your mailing address or the employer listed on your license, please go to *www.pharmacy.mt.gov,* click on the "Forms" tab, then in the left column click on "Address Change" or click on "General Forms" and then "Employment Change Form."
  - For other information or assistance, please contact the Licensing Unit A at 406/841-2205 or send an e-mail to the Board at dlibsdpha@mt.gov.
- **Meeting Dates:** The next Board meeting will be held on October 18, 2013, in Helena, MT. The remaining scheduled Board meetings include January 11, 2014, in Big Sky, MT, in conjunction with the Montana Pharmacy Association's meeting; and on April 11, 2014 and July 11, 2014 in Helena.
- **Newsletter:** Sign up for NABP's electronic delivery of this *Newsletter* by sending an e-mail to MontanaBoPNewsletter@nabp.net and type the word "Subscribe" in the subject heading.

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