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Montana Board of Pharmacy

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First Electronic Edition of the Montana Board of Pharmacy Newsletter

Welcome to the first edition of the electronic version of the Montana Board of Pharmacy *Newsletter*. The Board *Newsletter* will now be published electronically every three months (January, April, July, and October). If you accessed this *Newsletter* by following the instructions on the postcard mailed to your home, or if you received the *Newsletter* by other means, please visit the NABP Web site and “opt-in” by navigating to the State Newsletters section, choosing Montana, and adding your e-mail address to the mailing list so that you will automatically receive future editions of the Board’s electronic *Newsletter*.

Montana Board of Pharmacy Personnel

Starla Blank is the new executive director of the Board of Pharmacy. Starla lives in the Helena area and works full time at the Board of Pharmacy office. Starla can be contacted at 406/841-2371 or via e-mail at sblank2@mt.gov.

Evelyn “Evie” Martin is the new program manager for the Board of Pharmacy. The program manager is responsible for coordinating Board meetings and business, maintaining the budget, and coordinating the license renewal processes. Prior to coming to the Board of Pharmacy, Evie was the program manager for the Board of Medical Examiners. Evie can be contacted at 406/841-2355 or via e-mail at emartin@mt.gov.

Marilyn Kelly-Clark was the program manager for the Board of Pharmacy prior to Evie. Marilyn is the Unit 2 supervisor for the Health Care Licensing Bureau of the Department of Labor and Industry. Marilyn oversees the day-to-day operations of 13 of the 21 health care licensing boards, including the Board of Pharmacy. Marilyn can be contacted at 406/841-2380 or via e-mail at mkelley-clark@mt.gov.

Bill Sybrant is the Board of Pharmacy inspector. Bill resides in Great Falls, MT, but he travels extensively due to the nature of his job. Bill can be contacted at 406/439-6015 or via e-mail at bsybrant@mt.gov.

Nancy Dunagan is the licensing specialist for the Board of Pharmacy. Nancy is responsible for processing initial pharmacy applications and updating changes to pharmacy licenses (name, address, employer, pharmacist-in-charge (PIC), pharmacy ownership). Nancy can be contacted at 406/841-2356 or via e-mail at ndunagan@mt.gov.

A Reminder from your Board Inspector with Regard to Pharmacy Inspections

By Bill Sybrant, Board Inspector

A completed on-site inspection is not a guaranteed stamp of approval that a site is 100% compliant. During routine inspection,

which can last anywhere from one-half hour to several hours, it is impossible to inspect every aspect of a pharmacy’s operation. It is completely possible that a deficiency or an area of noncompliance may go unnoticed during an inspection. The fact that a specific problem or condition was not identified previously does not mean that the pharmacy cannot be cited simply because it has been occurring for years and was not detected or noticed before. The PIC is ultimately responsible for ensuring that the pharmacy and its staff are in compliance with all pharmacy laws and rules regardless of what the inspector may or may not have observed during previous inspections. All pharmacy staff should understand the significance of the PIC position and how the PIC is looked to by the Board when it needs specific questions answered involving his or her pharmacy.

A citation may be issued for noncompliance during a routine inspection and is issued to the PIC, the pharmacy, or in some situations, to both. Conditions in a pharmacy that are unsatisfactory or require improvement must also be corrected within the time frame indicated on the inspection form by the next routine inspection in order to avoid a possible citation. As always, I appreciate your continued efforts to remain compliant in your practice of pharmacy throughout Montana. I may be reached at 406/439-6015 or bsybrant@mt.gov to answer your questions.

Registration of Pharmacy Technicians

By Nancy Dunagan, Licensing Specialist

The Board of Pharmacy office receives numerous calls regarding registration of pharmacy technicians, and there is confusion regarding national certification and state registration. In order to perform pharmacy technician duties in Montana, one needs to be registered with the Board of Pharmacy. Montana has a two-tiered registration system for technicians. A technician candidate who has passed the Pharmacy Technician Certification Board (PTCB) examination will be registered as a certified pharmacy technician. The certified pharmacy technician application, instructions, and the Administrative Rules governing technician duties are available on the Board of Pharmacy Web site at www.pharmacy.mt.gov.

A technician candidate who has not taken the PTCB examination, would register to become a technician-in-training. A technician-in-training has 18 months from the date of registration to pass the PTCB examination. The technician-in-training registration is not renewable. Registration packets for the PTCB examination may be obtained from the Montana Pharmacy Association by contacting 406/449-3843. Once the PTCB examination has been passed, it is the responsibility of the technician to send a copy of the certificate to the Board of Pharmacy office. When the Board office has received the PTCB certificate and the technician file is complete, the

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FDA Launches Consumer Educational Program on the Safe Use of OTCs

The United States Food and Drug Administration's (FDA) Center for Drug Evaluation and Research, in cooperation with the National Council on Patient Information and Education and Maryland's Montgomery County Public Schools, has launched "Medicines in My Home," an interactive educational program aimed at informing middle school students about the safe and effective use of over-the-counter (OTC) medicines. Key concepts students will learn from the program are:

- ◆ the Drug Facts label tells you what a medicine treats, if it is right for you and your problem, and how to use the medicine;
- ◆ read the label and follow the directions carefully and correctly;
- ◆ two medicines with the same active ingredient should not be used at the same time; and
- ◆ measure medicines correctly with measuring tools made for medicines.

The program emphasizes that medicines should be used only with permission from an adult and that if there are questions about medicine use, ask a pharmacist or doctor. Materials are provided to encourage students to share what they learn with their families so that all family members can learn to use OTC medicines more safely. Program information can be found at www.fda.gov/medsinmyhome.

HHS Warns Public of Heroin and Fentanyl Deadly Combo

In efforts to warn the public and health care professional communities regarding a recent rash of drug-related deaths due to an illicit street drug combination consisting of the prescription medication fentanyl and either heroin or cocaine, the Department of Health and Human Services (HHS) released a fact sheet containing specific information with the goal of saving lives.

A letter from H. Westley Clark, director of HHS Center for Substance Abuse Treatment, to health care professionals warned that in "just one week, an estimated 33 individuals in the Detroit, MI area are reported to have died after using this fatal mix of drugs; the same drug combination may have been responsible for more than 100 deaths in the same region last September [2005]." Philadelphia, PA; Chicago, IL; St Louis, MO; and Camden, NJ have also recently experienced similar clusters of drug-related deaths.

Fentanyl, an injectable Schedule II prescription opioid analgesic, is roughly 50 to 80 times more potent than morphine but can also be produced in clandestine laboratories in powder form and then mixed with or substituted for heroin. Fentanyl-related overdoses can result in sudden death through respiratory arrest, cardiac arrest, severe respiratory depression, cardiovascular collapse, or severe anaphylactic reaction. In some cases, heroin or cocaine users are aware they are purchasing this dangerous combination of drugs and in other cases, they are not. Because the potency of street-sold heroin or cocaine is amplified markedly by fentanyl and because the inclusion of fentanyl

may not be disclosed, any use, even a reduced dose, can result in overdose or death. The fact sheet advises that suspected overdoses should be treated rapidly with a naloxone injection, 0.4 to 2 mg intravenously, subcutaneously, or intramuscularly every two to three minutes, which should rapidly reverse symptoms related to a narcotic overdose; if there is no response after 10 minutes, then a different diagnosis should be considered.

For additional information, contact Kenneth Hoffman at the Substance Abuse and Mental Health Services Administration at 240/276-2701 or via e-mail at Kenneth.Hoffman@samhsa.hhs.gov.

Pharmacy Technicians and Medication Error Prevention



This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing 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, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

In an October 2005 article in the *American Journal of Health-System Pharmacists*, the results of a random nationwide survey of more than 800 pharmacy technicians' views about their medication errors was published (Desselle SP. Certified pharmacy technicians' views of their medication preparation errors and educational needs. *Am J Health-Syst Pharm*. October 1, 2005; 62:1992-97). Most of the technicians worked in community pharmacies, but more than a quarter (27%) were employed in hospitals.

As one might expect in both settings, interruptions and inadequate staffing were among the most frequent factors perceived to contribute to technician medication preparation errors. Inadequate staffing was perceived as especially problematic in chain pharmacies, while inadequate supervision by pharmacists was cited as a factor more frequently by hospital technicians. It also may come as no surprise that the pharmacists' most frequently cited response to an error that was caught during the checking process was to make the technician aware of the error and require him or her to correct it. However, only about 17% of the technicians reported that the pharmacist had used the error as an opportunity to provide instructions on how to avoid the same or similar errors in the future.

While many of these respondents attributed this responsibility to the organization as a whole, not necessarily the individual pharmacist who detects an error, it appears technicians may not be receiving guidance about system and process changes that can help avert errors. After an



error is corrected, the checking pharmacist should find time that same day (or the next day, if necessary) to review the error with the technician and suggest ways to avoid it, including safer behavioral choices if applicable. Later, during pharmacy staff meetings or other forms of intradepartmental communication, errors, their causes, and ways to prevent them should be shared with all staff in a way that does not embarrass those who were possibly involved in the errors.

One or Both Nostrils?

Submitted by ISMP

Although many nasal sprays are intended for administration in each nostril for a single dose, there are notable exceptions. For example, some medications are meant to be delivered via the nasal passage but **not** sprayed into each nostril. Calcitonin salmon (**Fortical**[®], **Micalcin**[®]) is a prime example. Patients should administer a single spray (200 international units) into one nostril daily, using alternate nostrils each day. Other examples in metered-dose or unit-dose nasal spray containers include butorphanol, desmopressin (**DDAVP**[®]), sumatriptan (**Imitrex**[®]), and zolmitriptan (**Zomig**[®]).

Some pharmacy and/or physician electronic prescribing systems have been preprogrammed to print directions that default to "spray in each nostril" when nasal sprays are selected. For the previously mentioned drugs, this would result in the administration of a double dose of medication. One health care facility recently reported that about 50 patients, who had been prescribed medications intended to be given into one nostril, had prescription container labels that instructed the patients to administer the spray into both nostrils. Some physicians might anticipate patients' confusion and write the prescription for "half" doses in each nostril. Even if instructed to use the spray in one nostril, patients who administer other nasal medications in both nostrils may spray these medications into both nostrils without thinking.

Explicit verbal directions and written instructions that emphasize administration via one nostril only are critical to avoid an overdose.

FDA/ISMP National Campaign to Help Eliminate Ambiguous Medical Abbreviations

FDA and the ISMP have launched a national education campaign that focuses on eliminating the use of potentially harmful abbreviations by health care professionals, medical students, medical writers, and the pharmaceutical industry. The campaign addresses the use of error-prone abbreviations in all forms of medical communication, including written medication orders, computer-generated labels, medication administration records, pharmacy or prescriber computer order entry screens, and commercial medication labeling, packaging, and advertising. For more information visit www.fda.gov/cder/drug/MedErrors.

DEA Provides Retail Training Materials

Drug Enforcement Administration (DEA) recently announced the availability of training materials regarding self-certification training for regulated retail sellers of non-prescription drug products containing

ephedrine, pseudoephedrine, and phenylpropanolamine as required by the Combat Methamphetamine Epidemic Act of 2005 (Title VII of Public Law 109-177).

Two sets of training materials have been developed: one for regulated persons who are mobile retail vendors, and one for regulated persons who are not mobile retail vendors. Both sets of training materials may be found on the Diversion Control Program Web site, www.deadiversion.usdoj.gov, under "Combat Methamphetamine Epidemic Act of 2005."

DEA notes that regulated sellers must use the content of these training materials in the training of their employees who sell scheduled listed chemical products. A regulated seller may utilize additional content in its training program, but DEA's posted material must be included.

DEA is continuing to work to promulgate regulations to implement the Combat Methamphetamine Epidemic Act of 2005.

FDA Announces Release of Guidance on Useful Written Consumer Medication Information

In the July 18, 2006 *Federal Register*, FDA announced the availability of a guidance entitled "Useful Written Consumer Medication Information (CMI)." This guidance is intended to assist individuals or organizations (eg, pharmacies, private vendors, health care associations) in developing useful written consumer medication information to comply with Public Law 104-180. CMI is written information about prescription drugs developed by organizations or individuals, other than a drug's manufacturer, that is intended for distribution to consumers at the time of dispensing. Since neither FDA nor the drug's manufacturer reviews or approves CMI, FDA recommends that the developers of written medication information use the factors discussed in this guidance to help ensure that their CMI is useful to consumers.

This guidance can be accessed at www.fda.gov/cder/guidance/7139fnl.htm.

2007 Survey of Pharmacy Law Available Soon

NABP's 2007 *Survey of Pharmacy Law* CD-ROM will be available in early December 2006. New topics include whether or not licensure for wholesale distributors of non-prescription drugs is required and the recognition of Verified-Accredited Wholesale Distributors[™] accreditation.

The *Survey* consists of four sections: organizational law, licensing law, drug law, and census data. The *Survey* can be obtained for \$20 from NABP by downloading the publication order form from www.nabp.net and mailing in the form and a money order to NABP. The CD-ROM is provided free of charge to all final-year pharmacy students through a grant from AstraZeneca Pharmaceuticals. If you do not have Web access or would like more information on the *Survey*, please contact NABP at 847/391-4406 or via e-mail at custserv@nabp.net.

status of the registration will change from technician-in-training to certified technician.

Certified technician registration in Montana is an annual renewal with an expiration date of June 30 of every year. The Montana Board of Pharmacy does not require technicians to submit proof of PTCB certification or continuing education (CE) upon license renewal. The Board performs a random yearly audit of certified pharmacy technicians licensed in Montana to assure that PTCB certification is current.

Renewal of the PTCB certification is due every two years on the anniversary of the date of the PTCB examination. Documentation of CE is required by PTCB upon renewal. Information about PTCB renewal and CE requirements is available at the PTCB Web site at www.ptcb.org.

Review of Requirements for CEAC Approval

By Starla Blank, Executive Director

The Montana Board of Pharmacy office has received an increased number of requests for Continuing Education Advisory Council (CEAC) approval for educational programs, so a review of the requirements is a timely topic.

A CEAC Program Approval Form must be submitted with every request for CEAC approval. The Form, which has been revised as of July 2006, outlines all of the information that must be submitted to the Board. An electronic copy of the Form can be obtained from the Board of Pharmacy office by e-mailing a request to dlibsdp@mt.gov.

A copy of the presenter's curriculum vitae (CV) should be provided when requesting program approval. If a CV is not available, a summary of the presenter's credentials, professional affiliations, and current practice site(s) is acceptable. The presenter's name and credentials alone on a program flier will not be accepted.

A description of the program content must be submitted. The Board must have enough information to make an evaluation of the educational content of the program. This may be a summary of the program with goals and objectives or a copy of the entire presentation. A program flier with the title of the presentation, the presenter's name, and program date, time, and location does not provide enough information to determine the educational value of a presentation and will not be accepted.

Once a program has been CEAC-approved, the requester must award each attendee a certificate indicating the program title, CEAC number, hours approved for group or individual credit, program date, and attendee name. The requester must maintain a copy of all materials submitted to the Board, the attendee sign-in sheet, and the CEAC approval letter for three years.

New and Amended Board of Pharmacy Rules Effective July 1, 2006

The following is a summary of the new rules that went into effect on July 1, 2006. For a complete listing, visit the Board of Pharmacy Web site www.pharmacy.mt.gov.

Registration of Ambulatory Surgical Facilities: This new rule states that the Board shall annually register and inspect all ambulatory surgical facilities in Montana, regardless of pharmacy status. In ambulatory surgical facilities without an on-site pharmacy, drug distribution must be directed by a physician or a Montana-licensed consulting pharmacist who is responsible for the security, storage, and distribution of drugs within the facility.

Inactive Pharmacist License: This new rule allows a pharmacist to obtain an inactive license through a written request to the Board of Pharmacy. The annual renewal fee for the inactive pharmacist license is \$25.

Remote Telepharmacy Operation: This new rule allows for a remote telepharmacy site to be connected to its parent pharmacy via computer, video, and audio link. A site cannot be licensed as a remote telepharmacy if it is located within a 10 mile radius of an existing pharmacy. A remote telepharmacy site must be manned by a registered pharmacy technician in good standing. The remote telepharmacy site is considered to be under the personal charge of the pharmacist at the parent pharmacy. The operation of the remote telepharmacy shall

comply with all the requirements of pharmacy rules and statutes of Montana. If controlled substances (CS) are dispensed or handled, both the remote telepharmacy site and the parent pharmacy must be registered with Drug Enforcement Administration (DEA) and must obtain separate DEA license numbers. No prescription medication may be released to a patient until approved by a pharmacist in person or via the computer, video, and audio link. Monthly inspections of the remote telepharmacy site are required to be completed by the pharmacist at the parent pharmacy or that person's designee, and those reports must be available for review for the Board of Pharmacy inspector during a Board inspection.

Remote Telepharmacy Dispensing Machine Sites: This new rule is a variant of the Remote Telepharmacy rule wherein the telepharmacy site utilizes both a pharmacy technician and a computerized dispensing machine at the remote site.

Central Filling by Hub Pharmacies: This new rule will allow prescriptions to be filled at either a remote pharmacy or at a central hub pharmacy and then transferred securely back to the remote pharmacy. Both the central hub pharmacy and the remote pharmacy must be staffed by licensed pharmacists. A pharmacist shall offer patient counseling at either pharmacy site.

The following is a summary of the amendments to existing rules that went into effect on July 1, 2006. For a complete listing, please visit the Board of Pharmacy Web site at www.pharmacy.mt.gov.

Change in Address and/or Employment 24.174.403: A licensee shall notify the Board in writing within 10 days of any change in employment, and/or any change of business or personal address.

Transfer of Prescriptions 24.174.514: The rule for transfer of prescriptions was amended to address procedures for both the manual and electronic transfer of prescription information. Since the procedures differ in several ways, manual and electronic methods of prescription transfer have been separated into two distinct sections of the rule.

Noninstitutional Collaborative Practice Requirements 24.174.524: Collaborative practice agreements approved by an institutional committee, such as a Pharmacy and Therapeutics Committee that will be used solely for inpatients, do not require the approval of the Board of Pharmacy.

Tasks and Functions of a Pharmacy Technician 24.174.705: This rule was amended to allow a pharmacy technician to act as an agent in charge of the pharmacy when a registered pharmacist is not physically present. The technician may not perform duties that require the professional judgment of a pharmacist, and the technician may not be left in charge of the pharmacy for more than 30 minutes.

Ratio of Pharmacy Technicians to Supervising Pharmacists 24.174.711: This rule was amended to allow a pharmacist to supervise no more than three technicians at any time. If a pharmacy desires more than three technicians to work under the supervision of one pharmacist, the pharmacy shall obtain prior written approval of the Board.

Security of a Pharmacy 24.174.814: This rule was amended to require all pharmacies to maintain and reconcile a perpetual inventory of Schedule II CS. Many pharmacies already engage in this safety practice, which allows for the earliest detection of errors or diversion.

Wholesale Drug Distribution Licensing 24.174.1201: This rule was amended to require a wholesale distributor of prescription drugs to license each separate facility where drugs are stored or distributed.