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Montana Board of Pharmacy

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Inactive Pharmacist License

A new rule went into effect in June 2006, which created an inactive pharmacist license (24.174.504 ARM). A written request must be submitted to the Montana Board of Pharmacy in order to obtain an inactive license. The annual fee for the inactive license is \$25. Pharmacists who obtain an inactive license are still required to complete 15 hours of continuing education (CE) per year, with a minimum of five hours in a group setting and to renew the inactive license annually. Please contact the Board of Pharmacy office at 406/841-2371 if you are considering obtaining an inactive license, or if you would like more information.

Rule Notice Pending

A notice of amendment, adoption, and repeal of pharmacy rules will be published in the near future and posted on the Board of Pharmacy Web site (www.pharmacy.mt.gov). Every licensee will receive notification via United States mail when the rule notice is published and available online. Written comments on the rules may be sent to the Board via US mail or e-mail. A public hearing will be scheduled, which will give licensees and other interested parties the opportunity to provide verbal comments to the Board. Please exercise your right to give the Board feedback on the proposed rule changes, which may directly affect your practice.

Pharmacist and Certified Technician License Renewal

License renewal time is near. Renewal notices for pharmacists and certified pharmacy technicians will be mailed from the Board office on May 1, 2007. The renewal notices are in the form of flyers, which will be sent to the addresses that the Board has on record. It is each licensee's responsibility to contact the Board of Pharmacy office within 10 days of a change in employment, business address, or home address (24.174.403 ARM).

The renewal flyer clearly states "Renewal Notice" and "Do not discard." The flyer contains information on how to renew your license online and includes a personal identification number (PIN), which is required for online license renewal. If you choose not to renew online, you may download a license renewal form from the Board of Pharmacy Web site (www.pharmacy.mt.gov). **The flyer is not the renewal form. Please do not send in the flyer with payment. A renewal form must be received.** If you do not have access to a computer, contact the Board office at 406/841-2356 or 406/841-2355 to have a renewal form faxed or mailed.

Pharmacists – upon license renewal, you must attest that you have not had any legal or disciplinary actions against your license since the last renewal and that you have completed the required CE, a total of 15 hours with a minimum of five hours in a group setting (ARM 24.174.2104). The random CE audit will commence the first week in July per ARM 24.174.2103 (3) (a).

Certified pharmacy technicians – upon license renewal, you must attest that you have not had any legal or disciplinary actions against your license since the last renewal and that you have a current Pharmacy Technician Certification Board (PTCB) certificate. The random PTCB certificate audit will commence the first week of July per ARM 24.174.2102 (2).

Answers to Frequently Asked Questions

Is there a quantity limit on Schedule II prescriptions? According to federal law, there is no quantity limit for controlled substances (CS) prescriptions, including Schedule II prescriptions. However, a pharmacist has the obligation to verify that the prescription is valid and that the quantity is reasonable for the particular circumstance.

Some practitioners with prescriptive authority have quantity limitations on CS prescriptions by Montana

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FD&C Act Holds Manufacturers Accountable for Availability of Medication Guides

Under the Federal Food, Drug, and Cosmetic (FD&C) Act, Food and Drug Administration (FDA) requires that Medication Guides be dispensed with products the agency deems a serious and significant public health concern. Medication Guides provide consumers with information about the risks and benefits of these drugs and are necessary for patients to use these products safely and effectively.

FDA is interested in receiving reports about all instances in which manufacturers, distributors, or packers are not complying with the Medication Guide distribution requirements as set forth in Title 21, Code of Federal Regulations (CFR), section 208.24, Distributing and dispensing a Medication Guide.

The regulation requires manufacturers, distributors, or packers to provide authorized dispensers with Medication Guides – or the means to produce Medication Guides – in sufficient numbers to provide one to each patient who receives the drug. The manufacturer is responsible for ensuring that pharmacists have the Medication Guides they need when dispensing these drugs to consumers.

Problems related to the availability of Medication Guides are a labeling concern to FDA, and pharmacists are often the first to become aware of these problems. Voluntary reporting by pharmacists of these instances would assist FDA in ensuring manufacturer, distributor, and packer compliance with the Medication Guide regulatory requirement.

In addition to reporting to FDA, the agency advises pharmacies to contact the manufacturers directly to discuss problems associated with the availability of Medication Guides.

More information is available at www.fda.gov/medwatch/report/hcp.htm. Reports can also be made by phone at 1-800/FDA-1088.

Infant Deaths Attributed to Cough and Cold Medications

The Centers for Disease Control and Prevention (CDC) issued a Morbidity and Mortality Weekly Report article describing three deaths of infants ranging in age from one to six months associated with cough and cold medications. These medications were determined by medical examiners or coroners to be the underlying cause of death.

According to the report, the three infants – two boys and one girl – had what appeared to be high levels (4,743 ng/mL to 7,100 ng/mL) of pseudoephedrine in postmortem blood samples. One infant had received both a prescription and an over-the-counter (OTC) cough and cold combination medication at the same time; both medications contained pseudoephedrine.


During 2004-2005, an estimated 1,519 children younger than two years were treated in emergency departments in the United States for adverse events, including overdoses, associated with cough and cold medications.

Because of the risks, parents and caregivers should consult a health care provider before administering cough and cold medications to children in this age group. Clinicians should use caution when prescribing cough and cold medications to children younger

than two years. In addition, clinicians and pharmacists should always ask caregivers about their use of OTC combination medications to avoid overdose from multiple medications containing the same ingredient.

The complete article is available at www.cdc.gov/mmwr/preview/mmwrhtml/mm5601a1.htm.

Changes in Medication Appearance Should Prompt Investigation

 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.

As the number of generic products continues to increase, it seems that both patients and practitioners have become desensitized to changes in medication appearance. So much so that patients may not question a change or, when they do, practitioners may simply reassure them that it was due to a change in manufacturer without actively investigating the reason. It is not uncommon for ISMP to receive reports from both practitioners and consumers where a change in medication appearance was not fully investigated and subsequently contributed to an error.

In one case, a man shared an account of what his 86-year-old father experienced over the course of nine days after his prescription for minoxidil was mistakenly refilled with another medication. He had been taking minoxidil 2.5 mg for years at a dose of 5 mg (2 tablets) twice daily. Due to failing vision, he did not realize that his minoxidil tablets looked different. His daughter noticed the change, but was unconcerned since the tablets had previously changed appearance. Within a few days of taking the medication, his appetite began to fade, he complained of a sore throat, and felt like he was coming down with a cold. Soon after, he developed a red rash on his face, had trouble maintaining his balance, needed assistance with his daily activities, and wished to remain in bed. When a family friend (a nurse) came to see him, she noticed a very red, raised rash on his abdomen that looked like a medication rash. She asked his daughter if he was taking any new medications and was informed that there were no new medications, but the minoxidil tablets looked different than before. The pharmacy was contacted about the change and a staff member explained that it was a different generic for minoxidil, and that the pills could be exchanged for those that he usually received. There was no mention of a mistake being made when the medication was exchanged. He was taken to the hospital the following day, when he could barely walk.



After this incident was explained to hospital staff, they contacted the pharmacy. It was then revealed that he was given methotrexate by mistake because the bottles were stored next to each other. By this time, the man had taken 36 methotrexate 2.5 mg tablets, his white blood cell and platelet counts were extremely low, and he was in critical condition. We later learned that he passed away during that hospital visit.

In another case, a breast cancer patient went to her pharmacy to pick up a refill for **Femara**[®] (letrozole) but instead received the estrogen replacement product **femhrt**[®] (norethindrone and ethinyl estradiol). The patient recognized that the tablets were different, but after she read the label on the prescription bottle, which indicated Femara, she proceeded to use the tablets thinking the pharmacy used another manufacturer's product. After some time, she began to experience bloating, low back pain, and menstrual spotting. The error was discovered when she visited the clinic and the practitioner asked to see her medication. It is believed that disease progression had occurred secondary to the estrogen exposure, as evidenced by increased tumor markers. As a result of the error, chemotherapy was restarted.

The nature of these errors (wrong product dispensed on a refilled prescription despite a correct interpretation of the prescription) reinforces the need for the prescription verification process to be standardized. Verification should include comparisons of the pharmacy label with the selected manufacturer's product and the original prescription (whenever possible). In addition, the national drug code (NDC) number on the manufacturer's product should be compared to the NDC number in the pharmacy computer system. Pharmacies that utilize drug-imaging technology or bar code scanners as part of their verification process experience fewer of these errors.

Patients should be made aware of what their medication will look like and be educated to always question any change in its appearance. Pharmacies could consider software that allows a description of the medication's appearance to be printed on either the pharmacy label or receipt. Staff and patients should then be educated about proper use of this method. Ideally, pharmacists should proactively communicate with patients about the appearance of their medication by showing the medication to them during counseling and alerting them whenever a change occurs. Pharmacists should thoroughly investigate questions raised by patients or caregivers. Consider making it mandatory for pharmacists to investigate all inquiries related to changes in medication appearance. Although an auxiliary label can be placed on the medication container or the pharmacy receipt to alert the patient or caregiver that a change in appearance has occurred, the label may go unnoticed.

FDA Launches CDERLearn Educational Tutorial on MedWatch

FDA's Center for Drug Evaluation and Research (CDER) has launched its new Web-based self-learning tutorial, FDA MedWatch and Patient Safety, available at www.connectlive.com/events/fdamedwatch. This tutorial is intended to teach students in the health care professions and practicing health care professionals about FDA's Safety Information and Adverse Event Reporting Program, known as MedWatch.

The module explains how MedWatch provides important and timely clinical safety information on medical products, including prescription and OTC drugs, biologics, medical and radiation-emitting devices, and special nutritional products (eg, medical foods, dietary supplements, and infant formulas). It also describes how the reporting of serious adverse events, product quality problems, and product use errors to MedWatch is essential to FDA's safety monitoring process and to improving patients' safe use of medical products. The module consists of a 30-minute video and PowerPoint program with optional quiz and certificate of completion.

Three additional free programs for health professionals are available on the CDERLearn site, on the topics of the drug development and review process, the generic drug review process, and osteoporosis. Continuing education credit for these three programs may be awarded after completion of a quiz and evaluation form.

More information is available at www.fda.gov/cder/learn/CDERLearn/default.htm.

ONDCPRA Increases Patient Limit for Physicians Authorized under DATA 2000

The Office of National Drug Control Policy Reauthorization Act of 2006 (ONDCPRA) has modified the restriction on the number of patients a physician authorized under the Drug Addiction Treatment Act of 2000 (DATA 2000) may treat.

Under DATA 2000, physicians were restricted to treating no more than 30 patients at any one time. Under ONDCPRA, which became effective on December 29, 2006, physicians meeting certain criteria may notify the Secretary of Health and Human Services of their need and intent to treat up to 100 patients at any one time.

To be eligible for the increased patient limit: (1) the physician must currently be qualified under DATA 2000; (2) at least one year must have elapsed since the physician submitted the initial notification for authorization; (3) the physician must certify his or her capacity to refer patients for appropriate counseling and other appropriate ancillary services; and (4) the physician must certify that the total number of patients at any one time will not exceed the applicable number.

DATA 2000 allows qualified physicians to dispense or prescribe specifically approved Schedule III, IV, and V narcotic medications for the treatment of opioid addiction in treatment settings other than the traditional opioid treatment program (ie, methadone clinics). In addition, DATA 2000 allows qualified physicians who practice opioid addiction therapy to apply for and receive waivers of the registration requirements defined in the Controlled Substances Act.

More information is available by phone at 866/287-2728, via e-mail at info@buprenorphine.samhsa.gov, or online at www.buprenorphine.samhsa.gov.

Deadline Approaches for Pharmacists to Use NPI Numbers

The Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) require pharmacists to begin using the National Provider Identifier (NPI) by May 23, 2007. These provisions are intended to improve the efficiency and effectiveness of the electronic transmission of health information. Pharmacists can apply online or print an application for an NPI at <https://nppes.cms.hhs.gov>.

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statute or rule. According to state law (37-20-404 MCA), physician assistants (PAs) are limited to prescribing a 34-day supply of a Schedule II prescription. There are no quantity limits for PAs on other scheduled or non-scheduled medications.

According to administrative rule (24.159.1465 ARM), nurse practitioners shall follow quantity limits for Schedule II prescriptions as allowed by the Drug Enforcement Administration but are limited to prescribing a 90-day supply for CS prescriptions in Schedules III-V.

Is there a time limit on a Schedule II prescription?

According to federal law, there is no time limit for when a prescription for Schedule II medication must be filled after written. However, a pharmacist has the obligation to verify that there is a legitimate medical need for every Schedule II prescription that is filled.

Legislative Update

The Montana Legislature is currently in session. A brief description of the bills before the Montana Legislature that directly affect the practice of pharmacy follows.

House Bill (HB) 449 Rescheduling of Buprenorphine. This bill proposes to amend the Montana Controlled Substance Act to move buprenorphine from a Schedule V to a Schedule III CS. Rescheduling buprenorphine to a Schedule III CS will bring Montana into compliance with federal law. The Board of Pharmacy supports HB 449.

HB 536 Wholesale Drug Distributors – Licensing and Medication Integrity. This bill created new wholesale drug distributor statutes, which provide for stringent licensing requirements for wholesale drug distributors and require the establishment of electronic drug pedigrees. The Board supports the concept of protecting the integrity of drug supply chain, but spoke in opposition to the bill because it conflicts with the existing wholesale drug distribution statutes. The Board worked with the bill sponsors to draft an amended bill that incorporates the stringent licensing requirements for wholesale drug distributors and establishes a requirement for electronic pedigrees into existing statutes.

SB 326 Prescription Monitoring Program. This bill allows the creation of an electronic database containing CS prescription information submitted by Montana-licensed pharmacies. The database would be maintained by the Board of Pharmacy and could be accessed by prescribers and dispensers of CS for the purposes of protecting patient safety and inhibiting prescription drug abuse and diversion. The Board testified in support of a prescription monitoring program in Montana.

SB 397 Revise Pharmacy Laws to Allow Dispensing of Drugs at Employer-Based Clinics. This bill would allow practitioners working at an employer-based clinic to dispense prescription medications directly to patients seen at that clinic, regardless of the location in relation to

retail pharmacy services. The Board of Pharmacy testified in opposition to this bill because of the potentially detrimental impact on patient safety that could result from eliminating the double check of the pharmacist and having prescriptions filled at multiple facilities.

SB 521 An Act Prohibiting the Substitution of Anti-epilepsy Drugs Without Patient and Physician Consent. This bill, as amended, would require a pharmacist to obtain patient and prescriber consent prior to substituting generic for brand, brand for generic, or generic to generic for any drug used to treat epilepsy. The Board did not take a formal position on the amended bill.

The Board of Pharmacy strongly urges all pharmacists to contact their local legislators to express their support or opposition to the legislation that could directly affect pharmacy practice in Montana. Information about the status of each bill as well as contact information for legislators can be found at www.mt.gov. Click on “Legislative Session Information” then select “2007 Session (LAWS).” From there, you have many options including “Look Up Bill Information” and “Legislator Information.” Most legislators list their e-mail addresses in their profiles, and e-mail is a very easy and effective method to contact legislators to express your opinion about a specific bill.

Inspector’s Corner – Technician Licensing

A reminder from the Board of Pharmacy that technicians-in-training and certified technicians must be licensed by the Board before they begin training or working in a pharmacy. The pharmacist-in-charge may be subject to disciplinary action by the Board if a technician-in-training or a certified technician begins working in the pharmacy without proper licensure. Additionally, for certified pharmacy technicians, proof of current PTCB certification must be available at the place of employment and readily available for review by the inspector.

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