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Montana Board of Pharmacy

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What to do with Prescriptions when the Doctor Passes Away, Retires, or Relocates

Used with permission from the Kansas State Board of Pharmacy.

How does a pharmacist handle refill requests when a prescriber passes away, retires, or relocates his or her practice? The Montana Board of Pharmacy and the Board of Medical Examiners do not have regulations pertaining to the number of refills allowed under these circumstances.

The following response to the issue was provided by the Office of Drugs, the National Center for Drugs, and the Biologics, Food and Drug Administration (FDA).

It is well established that a prescription of a practitioner given to a patient signifies generally that a physician/patient relationship exists. This relationship also connotes that during the life of the prescription, the patient is under the practitioner's professional care and includes the number of authorized refills. It is our opinion that once a physician/patient relationship is dissolved, the prescription loses its validity since the physician is no longer available to treat the patient and oversee his [or] her use of the prescribed drug(s).

The Montana Board of Pharmacy recommends that if the pharmacist is aware of the situation, the pharmacist should counsel the patient to seek a new physician immediately. The patient should be able to obtain a sufficient amount of the prescribed drug of any unexpired prescription to carry over until the services of another physician are obtained. In some cases, obtaining the services of another physician may take 60 days or longer.

The key to this issue is [to utilize] professional judgment [by balancing patient safety and regulatory compliance]. The pharmacist can refuse to refill any prescription, if, in the pharmacist's professional judgment and discretion, the prescription should not be refilled.

Board of Pharmacy Meeting Dates

The Board of Pharmacy meetings are open to the public; time for public comment on issues not listed on the meeting agenda is allotted at the beginning of every meeting. The Board can not take action on an issue discussed during the public comment period, but it can decide to place the issue on a future agenda.

Agendas are posted on the Board of Pharmacy Web site, www.pharmacy.mt.gov, two weeks prior to the meeting. Generally a full Board meeting convenes at 1 PM on the first scheduled meeting day and reconvenes at 9 AM on the second scheduled meeting day. Board of Pharmacy meetings are scheduled through April 2008 as follows:

- ◆ July 16-17, 2007, in Helena
- ◆ October 30-31, 2007, in Helena
- ◆ January 24-25, 2008, in Fairmont in conjunction with Montana Pharmacy Association Winter Meeting
- ◆ April 22-23, 2008, in Helena

The Board of Pharmacy welcomes and encourages pharmacists, interns, and technicians to attend a Board meeting. Active and informed practitioners make the pharmacy profession stronger!

Recommendations for Medication Disposal

It is no longer acceptable to instruct patients to flush unused or unwanted medications due to concerns about contamination of the water supply. Many professional societies and patient advocacy organizations have published guidelines on how to safely dispose of medications. The following are guidelines from the American Pharmacists Association (APhA)

1. **Do not flush** unused medications. Recent environmental impact studies report that this practice could be having an adverse impact on the environment.
2. When discarding unused medications, crush solid dosage forms or dissolve in water (this applies for liquids also) and mix with kitty litter, coffee grounds, or other solid kitchen waste, then place in a sealed plastic bag before tossing in the trash to reduce the risk of poisoning children or pets.
3. Remove and destroy all identifying personal information on the label on the prescription container.
4. Check for approved state and local collection programs or with hazardous waste facilities.

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FDA Issues Guidance on Glycerin Testing to Prevent DEG Poisoning

Spurred to action by repeated instances of diethylene glycol (DEG) poisoning, Food and Drug Administration (FDA) recently issued a guidance for industry entitled "Testing of Glycerin for Diethylene Glycol." This guidance provides recommendations on testing that will help pharmaceutical manufacturers, repackers, and other suppliers of glycerin, and pharmacists who engage in drug compounding, to avoid the use of glycerin that is contaminated with DEG and prevent incidents of DEG poisoning.

DEG contamination of glycerin can be detected by using specific analytical test procedures described in the United States Pharmacopeia monograph for glycerin, which quantifies the amount of DEG present at a detection level of 0.1%, as recommended by the interagency Diethylene Glycol Contamination Prevention Workshop of 1997. The guidance is available on the FDA Web site at www.fda.gov/cder/guidance/7654fnl.htm. FDA is accepting electronic comments on the guidance at www.fda.gov/dockets/ecomments.

Improperly Compounded Colchicine Blamed for Recent Deaths

Compounded colchicine that was 10 times as potent as labeled was responsible for two recent deaths in Oregon and Washington, the *Portland Tribune* reported on April 27, 2007. State officials are investigating the drug's role in a third death, also in Oregon. The drug was sent to a Portland, OR, clinic by ApothéCure, Inc, a Dallas, TX-based compounding pharmacy that distributes its drugs throughout the country. The two patients who died had received injections of colchicine as a treatment for back pain. Lab tests revealed that the colchicine administered in the two deaths had a potency of 4 mg/ml, rather than the 0.5 mg/ml stated on labels. According to Gary A. Schnabel, executive director of the Oregon State Board of Pharmacy, ApothéCure, a licensed Texas pharmacy, may be operating as a manufacturer. Both the Oregon Board and the Texas State Board of Pharmacy have opened investigations into the incident. The Texas Board advised ApothéCure to stop making colchicine; the company agreed, the *Portland Tribune* reported. On May 2, FDA announced the recall of all strengths, sizes, and lots of injectable colchicine compounded and sold by ApothéCure within the last year. The FDA MedWatch Safety summary on this issue is available at www.fda.gov/medwatch/safety/2007/safety07.htm#Colchicine.

New Podcasts Provide Emerging Drug Safety Information

FDA recently supplemented its print- and Web-based public health advisories with the launch of an audio broadcast service providing emerging drug safety information. The broadcasts, commonly known as podcasts, can be transmitted to personal computers and personal audio players. The service is part of FDA's ongoing effort to broaden and speed its communications on the safety of marketed medications when unexpected adverse events are reported to FDA. Since FDA launched the service in February 2007, broadcasts have addressed the potential hazards

of local anesthetics used in hair removal; the voluntary market withdrawals of drugs to treat the symptoms of Parkinson's disease and irritable bowel syndrome; and serious adverse events associated with agents that reduce the need for blood transfusions in cancer patients. The broadcasts are available on the FDA Web site at www.fda.gov/cder/drug/podcast/default.htm.

Prevent Tragedies Caused by Syringe Tip Caps



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.

Over the past several years, there have been a number of reports where children have swallowed or choked on hypodermic syringe caps that were overlooked by parents and left on the syringes administering the medication. In 2001, a 5-month-old child asphyxiated when a cap from a Becton Dickinson 3 ml hypodermic syringe ejected into his throat during medication administration. In this case, a pediatrician provided the parents with the hypodermic syringe (without the needle) to administer Vantin[®] (cefepodoxime) suspension. With the cap intact, the father inserted the syringe into the Vantin, pulled back the plunger, and the medication flowed into the syringe. To him, the cap appeared to be part of the syringe. When he placed the syringe containing the medication into the baby's mouth, the cap flew off and became lodged in his airway. The baby was taken to the hospital where a procedure was performed to remove the cap; however, he did not survive.

Despite these reports, the mother of a 9-month-old child recently notified the Institute for Safe Medication Practices about a near fatal experience involving her child. Her community pharmacist gave her a parenteral syringe (without the needle) to help her accurately measure and administer an oral rehydration liquid for her daughter. Unfortunately, the pharmacist's good intention resulted in patient harm. The mother was unaware that the syringe tip held a small, translucent cap; however, despite this, she was able to withdraw the oral liquid. Then as she administered the liquid, the cap on the end of the syringe ejected and became lodged in the child's throat, causing airway obstruction. Fortunately, the child recovered.

Although parenteral syringes are not designed for oral administration, health care practitioners may provide them to patients or caregivers to measure oral liquids without realizing how dangerous this practice may be. Some syringe



manufacturers place the small, translucent caps on parenteral syringes packaged without needles as a protective cover. However, practitioners may not realize the cap is there or may not inform patients or caregivers of the need for its removal prior to use. The danger arises due to the fact that the cap does not provide a good seal. Subsequently, medications can be drawn into many of these syringes without removing the caps. If not removed before administration, the force of pushing the plunger can eject the cap and cause it to lodge in a child's trachea.

Safe practice recommendations: Consider the following strategies to help protect your patients from tragedies caused by syringe tip caps.

- ◆ **Increase awareness.** Share this and previous errors with staff to illustrate why parenteral syringes should never be used for oral liquid medications. Show staff a video from FDA and ISMP highlighting this issue (access the video link at: www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/transcript.cfm?show=3#6).
- ◆ **Product availability.** Ensure that oral syringes (without caps) or other appropriate measuring devices are readily available for distribution or purchase at your practice site. Verify that the dosage can be accurately measured using the oral syringe. It may be necessary to keep a few different sizes on hand to ensure proper measurement of smaller doses.
- ◆ **Limit access.** If parenteral syringes must be stocked for use with injectable products, purchase syringes that are not packaged with the translucent caps to minimize the likelihood of this error.
- ◆ **Warning labels.** Add warning labels that state, "not for use with oral liquids" to boxes or storage bins containing parenteral syringes.
- ◆ **Educate patients and caregivers.** Provide education to patients and caregivers regarding proper use of an oral syringe (or other measuring device). Demonstrate how to measure and administer the dose and inform them about how to clean the device, if it is to be reused. Several years ago, Becton Dickinson voluntarily elected to package parenteral syringes without the small caps in response to this serious issue. However, since some manufacturers still include a cap on parenteral syringes, the danger of asphyxiation with the cap is still present. We have again contacted FDA to alert them about this problem. They have stated that they will be following up with each syringe manufacturer with the goal to get the syringe caps removed. At the very minimum, we believe that the packaging of parenteral syringes should be required to clearly state, "not for oral use" or "not for use with oral liquids."

New FDA Web Page Warns Against Buying Isotretinoin Online

FDA has launched a special Web page to warn consumers about the dangers of buying isotretinoin online. Improperly used, isotretinoin can cause severe side effects, including birth defects and serious mental health problems. The Web page, www.fda.gov/buyonline/accutane, is positioned as a search result on Internet search engines when consumers initiate an online search for the drug under any one of its four names (isotretinoin is sold under the brand name of Accutane® and in generic versions called

Amnesteem™, Claravis™, and Sotret®). The Web page warns that the drug "should only be taken under the close supervision" of a physician and a pharmacist, and provides links to related information, including ways to check that drugs purchased online come from legitimate pharmacies.

To reduce risks, FDA and the manufacturers of isotretinoin have implemented a strict distribution program called iPLEDGE to ensure that women using isotretinoin do not become pregnant, and that women who are pregnant do not use isotretinoin. Isotretinoin is available only at pharmacies that are registered for this distribution program. Additionally, the distribution program is designed to prevent the sale of isotretinoin over the Internet. Dispensing must comply with the agency's risk management requirements.

Tampering Results in Misbranding of Ziagen as Combivir

GlaxoSmithKline and FDA warned health care professionals of an apparent third-party tampering that resulted in the misbranding of Ziagen® as Combivir® and employed counterfeit labels for Combivir tablets. Two 60-count misbranded bottles of Combivir tablets contained 300 mg tablets of Ziagen.

The counterfeit labels identified are Lot No. 6ZP9760 with expiration dates of April 2010 and April 2009. The incident appears to be isolated and limited in scope to one pharmacy in California.

Pharmacists are advised to immediately examine the contents of each bottle of Combivir in their pharmacies to confirm that the bottles contain the correct medication. If a bottle contains anything other than Combivir tablets, pharmacists are advised to notify the manufacturer.

The letter from GlaxoSmithKline and FDA, containing photos of actual Combivir and Ziagen tablets, is posted on the FDA Web site at www.fda.gov/medwatch/safety/2007/Ziagen_Dear_RPh_03-29-2007.pdf.

FDA Issues Halt on Manufacture, Distribution of Unapproved Suppository Drugs

FDA notified health care professionals and consumers that companies must stop manufacturing and distributing unapproved suppository drug products containing trimethobenzamide hydrochloride.

These products, used to treat nausea and vomiting in adults and children, have been marketed under various names, including Tigan®, Tebamide™, T-Gen, Trimazide, and Trimethobenz. Drugs containing trimethobenzamide in suppository form lack evidence of effectiveness. This action does not affect oral capsules and injectable products containing trimethobenzamide that have been approved by FDA.

FDA urges consumers currently using trimethobenzamide suppositories or who have questions or concerns to contact their health care professionals. Alternative products approved to effectively treat nausea and vomiting are available in a variety of forms.

The MedWatch safety summary and a link to the full press release are available at www.fda.gov/medwatch/safety/2007/safety07.htm#trimethobenzamide.

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5. Talk to your pharmacist. As medication experts, pharmacists are available to guide you on how to properly dispose of unused medications.

Board of Pharmacy Census

(As of May 1, 2007)

Pharmacist (total licensed in Montana)	1,649
Pharmacist (total working in Montana)	996
Registered Intern	209
Certified Pharmacy Technician	810
Technician in Training	189
Community Pharmacy	235
Institutional Pharmacy	88
Mail Order Pharmacy	298
Wholesaler	538
Dangerous Drug Researcher	3

A Review of Rules for Methadone and Suboxone for the Treatment of Pain and Addiction

Used with permission from the Washington State Board of Pharmacy.

The Board receives many calls about the administration and dispensing of methadone and Suboxone® (buprenorphine/naloxone). Methadone and buprenorphine may be used for the treatment of pain, and any pharmacy may dispense these drugs for that indication. . . .

Methadone may only be used to manage narcotic addiction or to detoxify a patient when the prescriber is registered by the Drug Enforcement Administration (DEA) and the federal Department of Health and Human Services as a narcotic treatment facility (NTF). In such cases, methadone may only be administered by the NTF. [There are no registered physicians and/or NTFs in the state of Montana.]

If an addicted patient is admitted to a hospital for a condition other than addiction, methadone can be administered in the same amount as the patient's NTF or an amount sufficient to keep the patient from going into withdrawal. Therapy can not be continued when the patient is discharged from the hospital, and the patient can not be given a discharge prescription for methadone.

Outside of the NTF, methadone can not be prescribed or administered to addicted patients. However, DEA regulations do allow a physician to personally administer, not prescribe, daily methadone doses for a period of up to three days.

The Drug Addiction Treatment Act of 2000 expanded the clinical context of medication assisted opioid addiction treatment by allowing qualified physicians to dispense, prescribe, and administer specifically approved Schedule III, IV, and V medications in settings other than NTFs. At the present time, Suboxone (buprenorphine/naloxone) and Subutex® (buprenorphine) are the only two Schedule III-V medications that have been approved by the FDA for treatment of opioid addiction. In order to prescribe these medications for maintenance of addiction, a physician must receive training and a special registration number from the DEA. An "X" preceding the first

letter of a DEA registration number indicates that the registrant has received the required training to prescribe Suboxone or Subutex. Any pharmacy may fill a Suboxone or Subutex prescription written by a qualified prescriber. A list of qualified physicians [by state] is available at www.buprenorphine.samhsa.gov by clicking on Physician Locator.

[Currently there are qualified physicians located in Montana.]

Lessons Learned from the 2007 Legislative Sessions

2007 was a busy legislative year for the practice of pharmacy. There were several pieces of legislation introduced by special interest groups that would have had a significant impact on the daily practice of pharmacy. Two bills in particular should serve as a wake-up call to the profession to try to do a better job of communicating with patients and to document and publicize the positive impact that pharmacists can have on patient safety.

Senate Bill (SB) 397, sponsored by Senator Kim Gillan at the request of the Employee Managed Benefits Service, proposed to revise pharmacy laws to allow physician dispensing at employer-based clinics. The proponents of the bill testified that physician dispensing would save the patient and the employer money by eliminating the need for pharmacy services. Proponents also testified that face-to-face patient education by pharmacists occurs infrequently due to busy pharmacist workloads, primary interaction with clerks or technicians, and mail-order pharmacy services.

Opponents to SB 397 provided testimony about the important role that pharmacists play in patient safety by providing drug therapy review and patient education. Opponents also argued that physician dispensing is unregulated and that dispensing authority can be delegated to unlicensed personnel, which may compromise patient safety.

Montana Executive Director Position

Starla Blank, PharmD, has accepted the position of clinical director at St Peter's Hospital, Helena, MT, effective May 14, 2007. The department expresses its gratitude for her guidance and exceptional work during her tenure as executive director of the Montana Board of Pharmacy. Montana is actively seeking an executive director. Information regarding position description, requirements, and salary parameters may be found on the Web site at www.pharmacy.mt.gov. The closing date for this position is July 18, 2007.

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