March 2006

Kansas State Board of Pharmacy

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www.kansas.gov/pharmacy/

Published to promote voluntary compliance of pharmacy and drug law.

Disciplinary Actions

Case No. 05-01 – Distributor assessed a fine of $500 for dispensing medications to individual in Kansas without being licensed as a pharmacy.

Case No. 05-30 – Pharmacy fined $500 for failing to have pharmacy technicians registered with Kansas State Board of Pharmacy. The licensee was also assessed a fine of $2,340 for operating a pharmacy in excess of 30 days without a pharmacist-in-charge.

Case No. 05-35 – Licensee diverted controlled substance (CS) from employer. Board accepted a voluntary surrender of license.

Case No. 05-47 – Licensee entered into Stipulation requiring five-year contract with Committee on Impaired Pharmacy Practice.

Case No. 05-51 – Aaron Gregory, #14-02219 – Pharmacy Technician – Overland Park. Drug diversion; Registration revoked.

Case No. 05-55 – Amanda Wright, #14-03208 – Pharmacy Technician – Augusta. Drug Diversion; Registration revoked.

Case No. 05-62 – Gabriel Pagano, #14-03846 – Pharmacy Technician – Olathe. Drug Diversion; Registration revoked.

Case No. 05-63 – Justin Olson, #14-03844 – Pharmacy Technician – Olathe. Had knowledge that fellow employee diverted drugs from employer and failed to cooperate with investigation; Registration revoked.

Case No. 05-64 – Ashley L. Tripp, #14-03842 – Pharmacy Technician – Olathe. Had knowledge that fellow employee diverted drugs from employer and failed to report theft to employer; Registration revoked.

Drug Destruction

The Board is often asked the best way for patients to dispose of unused or expired medications. There is not an easy answer to this question. In the past the advice was to throw the medication down the toilet, but this is no longer recommended because of the potential for environmental damage. At this time, the best option is to direct the customer to a local hazardous waste facility; however, some waste facilities do not take medicines so you should have an alternative option. If there is a Pharmacy Take-Back program in your area, you could refer the customer to them. The last option is to throw the drugs in the trash. If you advise them to throw the drugs in the garbage they should follow the following steps to lessen the potential for abuse and privacy issues and to improve safety.

1. Keep the medication in the original container with the child-proof lid attached.
2. Remove the patient's names if they are present on the container.
3. Add a small amount of water to the solid drug or an absorbent material such as Kitty Litter®, sawdust, or flour to liquid drugs before recapping.
4. Adding a nontoxic spice such as cayenne pepper is another idea to make the drugs unpalatable.
5. Double enclose the contained drugs in a bag or any other waste container, such as a brown paper bag, to prevent immediate identification of a drug container.
6. Place medicines in the trash as close to garbage pickup as possible.

Pharmacy Technician Ratio

During the 2004 Legislative Session, the Board was authorized by statute to adopt regulations setting the pharmacist to pharmacy technician ratio. The Board has studied this issue at length and adopted a regulation setting the ratio at 2:1. The Board reviewed expanding the ratio further to coincide with additional training of technicians because there appeared to be majority support for a change of 3:1. It is clear that prescription volumes are rising and pharmacists are being asked to interact meaningfully with the patient and provide increasing amounts of pharmacy patient care services. The Board believes that safety and quality of care for patients would not be compromised with proper management and organization used in conjunction with evolving technologies. The Board agreed that the ratio could be raised so long as there were improved competencies of technicians since everyone involved will have greater responsibility. Therefore, the Board agreed to amend the regulation permitting a 3:1 ratio so long as two of the three technicians have been nationally certified by a vendor that has been approved by the Board. Vendors such as the Pharmacy Technician Certification Board and the International Academy of Compounding Pharmacists would have an opportunity to come before the Board and have their programs approved. Technicians would then have some choice in which examination they would take. The Board further determined that a legislative change should be sought that required a super majority vote of the Board before the ratio could be changed in the future. Since there are six board members a super majority would require five affirmative votes before a change could be made.

National Pharmacy C

(Applicability of the contents of articles in the National Pharmacy Compli
and can only be ascertained by examining

DEA Releases Final Rule on Approved Narcotic Controlled Substances for Maintenance of Detoxification Treatment

According to the June 23, 2005 *Federal Register*, Drug Enforcement Administration (DEA) has amended its regulations (§1301 and §1306) to allow qualified practitioners not registered as a narcotic treatment program to dispense and prescribe to narcotic-dependent persons Schedule III, IV, and V narcotic controlled drugs approved by Food and Drug Administration (FDA) specifically for use in maintenance or detoxification treatment. This final rule is in response to amendments to the Controlled Substances Act by the Drug Addiction Treatment Act of 2000 (DATA) that are designed to increase and improve the treatment of narcotic addiction. In addition, the final rule is intended to accomplish the goals of DATA while preventing the diversion of Schedule III, IV, and V narcotic drugs approved for maintenance/detoxification treatment. This rule went into effect July 25, 2005.

Additionally, the ammended regulations require the practitioner to include on the prescription the identification number or written notice that the practitioner is acting under the good faith exception of §1301.28(e). In order to be valid, a prescription must be written for a legitimate medical purpose by a practitioner acting in the usual course of his or her professional practice. The prescription must also be dated as of, and signed on, the day issued and must contain the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use as well as the name, address, and registration number of the practitioner. Practitioners are not normally required to keep records of prescriptions issued, but DEA regulations require records to be kept by practitioners prescribing controlled substances listed in any schedule for maintenance or detoxification treatment of an individual.

Any practitioner who dispenses or prescribes Schedule III, IV, or V narcotic drugs in violation of any of the conditions as specified in §1301.28(b), may have their practitioner's DEA registration revoked in accordance with §1301.36.

Due to the potential for diversion, and in an effort to verify compliance with these regulations, DEA intends to conduct at least two regulatory investigations per field office per year of practitioners dispensing and prescribing to narcotic-dependent persons Schedule III, IV, and V narcotic controlled drugs approved by FDA specifically for use in maintenance or detoxification treatment.

How FDA Reviews Drug Names

By Carol Holquist, RPh, FDA, Office of Drug Safety

FDA has received approximately 18,000 reports of actual or potential medication errors since 1992 and continues to improve the process by which these errors are assessed. Over the past nine years, FDA has increased the safe use of drug products by minimizing user errors attributed to nomenclature, labeling, and/or packaging of drug products. The group in charge of these activities is the Office of Postmarketing Drug Risk Assessment (OPDRA) under FDA's Center for Drug Evaluation and Research. Ten clinical pharmacists and physicians make up OPDRA's medication error staff.

The Name Review Process

Since October 1999, OPDRA has reviewed approximately 400 drug products. Proprietary names undergo a multifactorial review designed to improve consistency and minimize risk due to sound-alike and look-alike names. The process includes:

- *Expert panel review*. An expert panel meets weekly to exchange opinions on the safety of a new proprietary name. The panel comprises OPDRA medication error prevention staff and representatives from the Division of Drug Marketing and Advertising Communications, who rely on their clinical, regulatory, and professional experiences to decide on the acceptablilty of a proprietary name.
- *Handwriting and verbal analysis.* These are conducted within FDA to determine the degree of confusion in visual appearance or pronunciation between the proposed proprietary name and names of other United States drugs. FDA health professionals (nurses, pharmacists, and physicians) are requested to interpret both written inpatient and outpatient prescriptions and verbal orders in an attempt to simulate the Rx ordering process.
- *Computer-assisted analysis.* Currently, OPDRA utilizes existing FDA databases to identify potential sound-alike and/or look-alike proprietary names. In the future, OPDRA plans to use validated computer software that will improve the ability to detect similarities in spelling and sound among proprietary names.
- *Labeling and packaging analysis*. OPDRA provides a safety assessment of the container labels, carton and package insert labeling, and proposed packaging of each product to identify areas of potential improvement.
- *Overall risk evaluation.* This final phase of the name review process weighs the results of each phase of the review as well as additional risk factors such as overlapping strengths, dosage forms, dosing recommendations, indications for use, storage, labeling, and packaging, and important lessons learned from the agency's post-marketing experience.

How Can You Help?

Pharmacists and other health professionals can assist FDA in minimizing medication errors by reporting any actual or potential medication errors to MedWatch, FDA's medical product reporting and safety information program launched in June 1993. All identification of reporter, institution, and patient are kept confidential and are protected from disclosure by the Freedom of Information Act.

Medication errors can easily be reported to MedWatch via telephone (1-800/FDA-1088), Web site (www.fda.gov/medwatch), and fax (1-800/FDA-0178). In addition, a standardized MedWatch adverse event reporting form (FDA Form 3500) is available to aid in submitting voluntary reports of medication errors. You should provide a complete description of the error; level of staff (eg, pharmacist, nurse, physician) involved; medication involved; patient outcome; setting of the incident (eg, inpatient, outpatient); relevent patient information (eg, age and gender); date of event; manufacturer of the drug; dosage form and strength; and size of container. Finally, you will need to check both "Product Problem and/or Adverse Event" and "other" on the form.

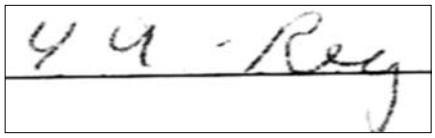
We also encourage you to include your suggestions for preventing errors. With your contributions to increased reporting and the new processes implemented by OPDRA, the agency can provide effective intervention strategies that will minimize the risks associated with medication errors.

What's wrong with "U?"

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, and 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.

The use of abbreviations is always problematic when communicating medical information. All too often, medical abbreviations hinder our understanding or are misread. Insulin errors are common and can cause significant patient harm. The cause of many insulin errors is related to the use of abbreviations when communicating prescription information. The abbreviation "U" to indicate "units" has contributed to many errors when it was misread as a zero (0) or a number 4.

Over the years, numerous reports have been received through the USP-ISMP Medication Errors Reporting Program that describe the occurrence of 10-fold or greater overdoses of insulin because the abbreviation "U" has been misinterpreted. It is not uncommon for a "U" to be misread as a zero (0). For example, prescriptions for "6U regular insulin" have been misinterpreted and administered as 60 units of regular insulin. In another report, a prescriber wrote an order for "4U Reg" (see photo); however, someone misinterpreted the "U" as a "4." The person who injected the insulin did not recognize that this was an excessive dose and proceeded to administer 44 units to the patient. The patient required glucose to reverse his acute hypoglycemia.



In order to prevent errors such as these, health care practitioners should **always** write out the word "units." Educate staff about the dangers involved with using this abbreviation. Practitioners must recognize the need for good communication skills and realize that the perceived time saved when using the abbreviation "U" for units may actually result in serious patient harm. Occasionally, while intending to do the "right thing," errors still can occur. This was the case when a physician wrote a sliding scale insulin order for a hospitalized patient with a blood sugar of 396 mg/dL. When writing the insulin order, the physician included the word "units." According to the order, this patient should have received 4 units of regular insulin subcutaneously. Unfortunately, because the letter "U" in units was separated from the rest of the word, "-nits," the nurse read the order as 40 units and administered the dose to the patient. His blood sugar dropped to 54 mg/dL and he required dextrose to correct the hypoglycemia. The error was realized when the nursing notes were reviewed and it was documented that 40 units was administered.

Pharmacy and nursing staff must carefully review insulin prescriptions, knowing that errors involving this abbreviation are common and can result in 10-fold or greater overdoses. Clarify any questionable insulin dosages and inform the prescriber of misinterpretations that could occur due to use of the abbreviation "U" for units. In addition, whenever possible, require an independent double check of insulin prescriptions before they are dispensed or administered.

Safeguards for Severe Acne Medication Announced

Because isotretinoin (Accutane®) carries significant risks of birth defects for women who are pregnant or might become pregnant, FDA has unveiled safeguards for its distribution. (See related article, March 2005 *NABP Newsletter*, page 61.) The manufacturers of isotretinoin are launching a program called iPLEDGE™ in which doctors and patients register with the program and agree to accept certain responsibilities as a condition of prescribing or using the drug. Wholesalers and pharmacies must also comply with the program to be able to distribute and dispense the drug.

In the wake of a February 2004 joint meeting between FDA's Drug Safety and Risk Management Advisory Committee and Ophthalmic Drugs Advisory Committee, major improvements were recommended for the restricted distribution program for isotretinoin, which has proven effective in treating severe recalcitrant nodular acne. Under the recommendations, patients who could become pregnant are to have negative pregnancy testing and birth control counseling before receiving the drug. In addition, patients must complete an informed consent form and obtain counseling about the risks and requirements for safe use of the drug. Starting December 31, 2005, all patients and prescribers must register and comply with requirements for office visits, counseling, birth control, and other program components. After October 31, 2005, wholesalers and pharmacies were required to register with iPLEDGE in order to obtain isotretinoin from a manufacturer.

Program information and registration is available at www.ipledgeprogram.com or 866/495-0654.

For the purpose of increasing available information about isotretinoin and its associated risks, FDA also issued a Public Health Advisory and revised the Patient and Health Care Provider Information Sheets that detail the new patient and practitioner restrictions and responsibilities under the program. A reporting and collection system for serious adverse events associated with the use of the drug has also been established. Pregnancy exposures to isotretinoin must be reported immediately to FDA at the MedWatch phone number (1-800/332-1088), the iPLEDGE pregnancy registry (866/495-0654), or on the iPLEDGE Web site.

Besides approving the iPLEDGE program, FDA approved changes to the existing warnings, patient information, and informed consent form to help patients and prescribers better identify and manage the risks of psychiatric symptoms and depression before and after taking the medication.

Physicians Writing Prescriptions for Themselves and Family Members

In Kansas, there is no prohibition against physicians writing prescriptions for themselves or family members, either for controlled or noncontrolled drugs, as long as the physician has an "Active" or "Exempt" license. They should, however, keep an adequate record (K.A.R. 100-24-1). Those with an "Inactive" license cannot engage in any practice, including writing prescriptions for themselves or family members.

What to Do When the Doctor Passes Away, Retires, or Relocates Practice

How do you handle refill requests when a prescriber passes away, retires, or relocates his or her practice? The Kansas Board of Pharmacy and Kansas Board of Healing Arts have no 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.

> 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 that 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 broken, 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 Kansas State 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 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 the pharmacist's professional judgement. As stated in K.S.A. 65-1637, the pharmacist can refuse to refill any prescription if, in the pharmacist's professional judgement and discretion, the prescription should not be refilled.

Frequently Asked Questions of DEA and Board – Agreed Upon Answers

Question: What changes may a pharmacist make to a prescription written for a CS?

Answer: The pharmacist may add the patient's address or change the patient's address upon verification. The pharmacist may change or add the dosage form, drug strength, drug quantity, directions for use, or issue date only after consultation with and in agreement of the prescribing practitioner. Such consultations and corresponding changes should be noted on the prescription as well as the patient's medical record. Pharmacists and practitioners must comply with any state/local laws, regulations, or policies prohibiting any of these changes to CS prescriptions. The majority of changes can be made only after the pharmacist contacts the prescribing practitioner. The pharmacist is never permitted to make changes to the patient's name, CS prescribed (except for generic substitution permitted by state law), or the prescriber's signature.

Question: Can a practitioner prescribe methadone for the treatment of pain?

Answer: Federal law and regulations do not restrict the prescribing, dispensing, or administering of any Schedule II, III, IV, or V narcotic medication, including methadone, for the treatment of pain, if such treatment is deemed medically necessary by a practitioner acting in the usual course of professional practice. Confusion often arises due to regulatory restrictions concerning the use of methadone for the maintenance or detoxification for opioid-addicted individuals, in which case the practitioner is required to be registered with Drug Enforcment Administration as a Narcotic Treatment Program.

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