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SC Department of Labor, Licensing, & Regulation – Board of Pharmacy

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Changes by DEA Regarding Reports by Registrants of Theft or Significant Loss of Controlled Substances

On September 12, 2005, the final rule amending Drug Enforcement Administration's (DEA) regulations regarding reports by registrants of theft or significant loss of controlled substances (CS) became effective. The rule amends §1301.74 and 1301.76 of Title 21 of the Code of Federal Regulations by requiring all DEA registrants to notify the DEA field office in their area **in writing** of any theft or significant loss of any CS within **one business day** of discovery of the theft or loss. Previously, registrants were required to report thefts and significant losses "immediately upon discovery." The "one business day" reporting requirement is in addition to the required reporting of the theft or significant loss on DEA Form 106, which may be submitted at a later date, once the circumstances surrounding the theft or significant loss are clear.

The final rule also amended DEA regulations to include factors to be considered when determining whether or not a loss is significant when reporting to DEA. The state of South Carolina regulations require that **all** thefts or losses be reported, so this additional amendment by DEA does not apply to DEA registrants in South Carolina. Additional information on this new amendment can be found on the DEA Diversion Web site, www.deadiversion.usdoj.gov, under "What's New." Click at the bottom of that section on "Click to Read More" and go to the date of August 12, 2005. New information regarding filing DEA Form 106 reports online is also available on the same Web site. The link to this new service is found on the right hand side of the home page of the Web site.

Registrants in South Carolina are required to report any theft or significant loss of CS to DEA and the South

Carolina Bureau of Drug Control. Registrants reporting only to the South Carolina Bureau of Drug Control have not met their requirement to report to DEA and may face administrative or civil actions for not doing so. All South Carolina registrants must report to both agencies independently as well as submitting the completed DEA Form 106 to each agency.

The "one business day" notification requirement noted may be sent by fax to the DEA Columbia, South Carolina Diversion Group at 803/253-3163 except for registrants in the following counties: Allendale, Beaufort, Berkeley, Charleston, Colleton, Dorchester, Georgetown, Hampton, and Jasper. Registrants in those counties should contact DEA's Charleston, SC office by fax at 803/308-6670.

For All Pharmacists – 2006 Renewal Notices

The 2006 renewal notices will be mailed to you on or about March 1, 2006. The South Carolina Board of Pharmacy has enhanced its online renewal system to make it easier and more convenient for you to renew your license. You will be mailed a renewal notice with a **User ID** and a **password** that will allow you to access the online renewal Web site (There will be a processing charge of \$1.25 added to your transaction.) If you choose not to renew online, you can request a renewal form from the Board and renew by mailing the completed form and proper fees to the Board. Applications submitted for renewal after April 1, 2006, must meet the renewal requirements and contain the appropriate fees. Applicants shall sign a pre-licensing agreement certifying that their license is subject to the right to impose sanction for unlicensed practice pursuant to §40-1-110 and §40-43-110(D). The following windows of time will be subject to additional penalties as listed on page four:

Continued on page 4



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 amended 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 acceptability 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); relevant 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.



Compliance News to a particular state or jurisdiction should not be assumed to be the law of such state or jurisdiction.)

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.

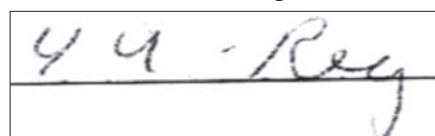
What's wrong with "U"?



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.

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- May 1-15, 2006..... Additional \$100
- May 16-31, 2006..... Additional \$150
- June 1-15, 2006..... Additional \$200
- June 16-30, 2006..... Additional \$250

After July 1, 2006, disciplinary proceedings before the full Board of Pharmacy will be required.

CE Reporting for Pharmacists

In order to renew online you must indicate that you have completed the required 15 hours of continuing education (CE). (Six hours must be live.) You cannot renew until you have completed the CE requirements. After renewals are processed, a random CE audit will be conducted. If you are selected for the audit, please respond promptly. Disciplinary action will be taken if you cannot show that you completed the CE requirements or if the required CE are dated **after** your renewal is received in the Board's office.

2006 Board of Pharmacy Meeting Dates

The South Carolina Board of Pharmacy will meet on the following dates:

- March 15, 2006 September 27-28, 2006
- June 28-29, 2006 November 15, 2006

All meetings will be held at the Board's office located in the Synergy Business Park, Kingstree Building, 110 Centerview Drive, Columbia.

2006 Pharmacy Technician Renewals

The 2006 renewal notices will be mailed to you on or about May 1, 2006. We have enhanced our online renewal system to make it easier and more convenient for you to renew your registration. You will be mailed a renewal notice with a **User ID** and a **password** that will allow

you to access the online renewal Web site (there will be a processing charge of \$1.25 added to your transaction). If you are a state certified pharmacy technician, you must mail a copy of your current National Certificate (from the Pharmacy Technician Certification Board) to the Board. If you choose not to renew online, you can request a renewal form from the Board and renew by mailing the completed form and proper fees to the Board. **Applications need to be received in the Board office by June 1, 2006.** Pharmacy technicians who do not renew prior to June 30, 2006, will be assessed penalties and shall not work as a pharmacy technician until a 2006-2007 registration is in hand or disciplinary action may result.

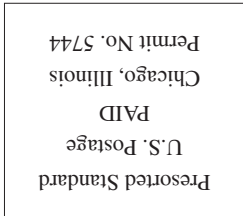
CE Reporting for Pharmacy Technicians

In order to renew online, you must indicate that you have completed the required 10 hours of CE (four hours must be live). You cannot renew until you have completed the CE requirements. After renewals are processed, a random CE audit will be conducted. If you are selected for the audit, please respond promptly. Disciplinary action will be taken if you cannot show that you have completed the CE requirements or if the required CE are dated **after** your renewal is received in the Board's office.

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