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New Jersey Board of Pharmacy

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www.state.nj.us/lps/ca/boards.htm

Published to promote voluntary compliance of pharmacy and drug law.

Continuing Education Credits for New Jersey Pharmacists

The New Jersey Board of Pharmacy is often asked what types of programs or courses qualify for continuing education (CE) credit for New Jersey pharmacists. New Jersey Administrative Code (N.J.A.C.) 13:39-3A.2 lists the types of programs that qualify for CE credit in New Jersey. Each pharmacist must complete at least 30 credits during each biennial period following the initial license renewal period, including a minimum of 10 didactic credits and three credits of pharmacy law. Acceptable sources of CE credit for New Jersey pharmacists are: (1) programs or courses offered by Accreditation Council for Pharmacy Education-approved providers; (2) programs or courses previously approved by the Board pursuant to N.J.A.C. 13:39-3A.6; (3) post-graduate courses relevant to pharmacy practice and completed at an accredited college or school of pharmacy; (4) active participation in a pharmacy-related teaching or research appointment; (5) active participation as a preceptor in a pharmacy internship or externship program; and (6) publication of a pharmacy-related article in a peer-review journal.

To obtain CE credit for any other type of program or course, including continuing medical education-approved courses, the applicant must contact the Board to obtain prior approval by requesting a CE Approval Form. This form must be completed and submitted to the Board along with a \$10 processing fee per course. The Board will in turn notify the applicant if the program qualifies for CE credit.

Facsimile and Electronically Transmitted Prescriptions

The requirements for prescriptions transmitted by facsimile or electronic means are not the same, as detailed in N.J.A.C. 13:39-7.10 and 13:39-7.11. Prescriptions transmitted by facsimile must meet all the requirements of N.J.A.C. 13:35-7.2(d), with the exception that a New Jersey Prescription Blank (NJPB) is not required: (1) full name, address, telephone number, license number, and proper academic degree or practice identification (ID) of the prescriber; (2) full name, address, and age of the patient; (3) date the prescription is issued; (4) name, strength, and quantity of the drug prescribed; (5) if a Schedule II drug, words as well as numbers indicating the quantity to be dispensed; (6) number of refills, time limit in which refills are permitted, or both; (7) handwritten original signature of the prescriber; (8) if a controlled dangerous substance (CDS), the Drug Enforcement Administration number of the prescriber; and (9) adequate patient instructions describing the frequency of drug administration. Additionally, facsimile prescriptions must also include: (1) the ID number of the facsimile machine; (2) the date and time that the prescription was sent by facsimile; (3) the name, address, telephone number, and facsimile number of the pharmacy; and (4) the full name and title of the authorized agent transmitting the prescription by facsimile. Schedule II prescriptions may be accepted by facsimile but

may not be dispensed until receipt of the original handwritten prescription with three exceptions: (1) a Schedule II compounded for direct parenteral (intravenous, intramuscular, subcutaneous, intraspinal) administration; (2) an oral or parenteral Schedule II prescribed for a resident of a long-term care facility; or (3) an oral or parenteral Schedule II prescribed for a hospice patient.

Prescriptions transmitted electronically must meet all the requirements of N.J.A.C. 13:35-7.2(d) as listed above with two exceptions: an NJPB and the original handwritten signature of the prescriber are not required. Schedule II prescriptions may not be dispensed prior to receipt of the original handwritten prescription unless permitted by federal law.

Labeling Requirements for Dispensed Retail Prescription Drug Containers

The affixed label for any dispensed retail drug container must contain the following information, as detailed in N.J.A.C. 13:39-7.12: (1) name and address of the dispensing pharmacy; (2) telephone number of the dispensing pharmacy; (3) brand name or generic name of the drug dispensed (manufacturer name must be included if the generic name is used); (4) medication strength; (5) quantity dispensed; (6) date dispensed; (7) CDS cautionary statement where appropriate; (8) name of the patient; (9) initials of the dispensing pharmacist; (10) name of the prescriber; (11) prescription number; (12) adequate directions for use; (13) "use by" date if dispensed in any package other than the manufacturer's original package (the "use by" date is one year from the dispensing date or one year from the expiration date on the manufacturer's original package, whichever comes first); (14) all auxiliary labeling as required by the manufacturer; and (15) additional patient directions or cautionary labels that, in the professional judgement of the dispensing pharmacist, should be added to ensure appropriate medication administration, storage, or use by the patient. Larger, bolded, or different color type must be used for the patient name, brand or generic medication name, and directions for use.

Disciplinary Actions

The actions listed below include only those where the individual's license to practice has been revoked, surrendered, suspended, restricted, or reinstated and do not include any other actions taken by the Board. Information regarding the current status of a pharmacist's license may be obtained either at the Division of Consumer Affairs Web site at www.state.nj.us/lps/ca/boards.htm or by calling the License Verification Line at 973/273-8090.

License Suspensions/Surrenders/Revocations

Yin Szeto, RPh – Respondent engaged in improper and unauthorized dispensing practices, and is incapable of discharging the functions of a registered pharmacist. On January 31, 2005, pursuant to the

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.

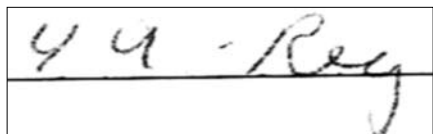
What's wrong with "U"?



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.

Continued from page 1

Order for Surrender of License, respondent shall cease and desist from engaging in the practice of pharmacy. Respondent's license will not be reinstated until respondent has demonstrated to the satisfaction of the Board that she is fit and competent to resume the practice of pharmacy. (Filed on February 3, 2005.)

Carl McClung, RPh – Respondent diverted CDS for his own use from his former employer's active drug stock. Respondent's license to practice pharmacy in the state of New Jersey was surrendered. Respondent shall cease and desist from engaging in the practice of pharmacy. Upon application for reinstatement, respondent shall submit documentation satisfactory to the Board inclusive of, but not limited to, weekly, random, witnessed urine screens, complete treatment records of all diagnostic and rehabilitative therapy and an in-depth, current evaluation from a Board-approved psychiatrist or psychologist. (Filed on March 10, 2005.)

Denise Fahmie, RPh – During the year 2004, respondent diverted from her employer's drug stock for her own consumption, 200 tablets of phentermine, a Schedule IV CDS, and 200 tablets of generic Fioricet®, a Schedule III CDS. Pursuant to the Order, respondent's license to practice pharmacy in the state of New Jersey was surrendered. Pending further order of the Board, respondent shall cease and desist from engaging in the practice of pharmacy. Upon application of reinstatement, respondent shall submit documentation satisfactory to the Board inclusive of, but not limited to, weekly, random, witnessed urine screens for a minimum of six (6) months, complete treatment records of all diagnostic and rehabilitative therapy and an in-depth, current evaluation from a Board-approved psychiatrist or psychologist. (Filed on March 23, 2005.)

Paul F. Cerza, RPh – By his own admission, respondent participated in the illegal distribution of prescription drugs. Pursuant to the Final Order set forth, respondent's license to practice pharmacy in the state of New Jersey has been suspended for a period of six (6) months. All of said suspension is stayed, to be served as probation. (Filed on April 28, 2005.)

Kenneth R. Horwitz, RPh – Respondent pled guilty in Passaic County to one count of Medicaid Fraud in the third degree. Respondent aided in the submission of claims for payment of approximately \$35,000 to the New Jersey Medical Assistance and Health Services Program for dispensing medications that in fact were not dispensed. Pursuant to the Consent Order set forth, respondent's license to practice pharmacy in the state of New Jersey has been revoked. (Filed on April 29, 2005.)

Alexander Q. Do, RPh – Respondent was convicted of eighteen (18) counts of the criminal sale of a controlled substance, a fourth-degree crime, and one (1) count of Grand Larceny, a third-degree crime in the state of New York. On May 16, 2005, respondent's license to practice pharmacy in the state of New Jersey was revoked with no right to request reinstatement prior to the termination of criminal probation or supervised release date of January 1, 2008. (Filed on May 24, 2005.)

Scott Stanislaw, RPh – On July 23, 2003, respondent was convicted of crimes of Conspiracy to Commit Wire and Mail Fraud, Wire Fraud, and four (4) counts of Mail Fraud in the southern district of Florida. Respondent was sentenced to eighteen (18) months of incarceration, supervised release for three (3) years, and restitution of \$578,851.09. Respondent's license to practice pharmacy in the state of New Jersey is suspended until January 9, 2008, the date on which respondent's probation or supervised release will terminate. (Filed on May 24, 2005.)

Reinstatements

Guiseppe Cucaro, RPh – *Past History:* Pursuant to a Consent Order dated, May 12, 2004, respondent surrendered his license in connection with allegations that he had diverted controlled substances for his own use. Respondent continues to deny any substance abuse issues and has not, therefore, participated in any rehabilitation program. As of March 2, 2005, respondent has entered into a Consent Order to reinstate his license to practice pharmacy with a probationary period of at least one (1) year, subject to random urine sampling two (2) times per week for the first six (6) months and thereafter one (1) time per week for the duration of the probation. (Filed on March 3, 2005.)

Joseph Chebli, RPh – *Past History:* Pursuant to a Consent Order filed on November 6, 2003, respondent surrendered his license, which was deemed a revocation. After respondent has submitted documentation of successful completion of thirty (30) current CE credits, ten (10) of which shall be didactic, pays all required fees, and completes a satisfactory criminal background check, his license to practice pharmacy will be reinstated. (Filed on April 28, 2005.)

Irina Risin, RPh – *Past History:* In connection with substance abuse issues, respondent voluntarily surrendered her pharmacy license and entered into a Consent Order on January 2, 2001. As of April 27, 2005, respondent entered into an Order with the Board to reinstate her license to practice pharmacy pending documentation of successful completion of thirty (30) CE credits, and an in-depth psychological evaluation by a Board-approved psychologist or psychiatrist. Upon satisfaction of aforementioned, respondent's license will be reinstated with a probationary status for six (6) months, during which time she will be subject to random urine monitoring. (Filed on April 28, 2005.)

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