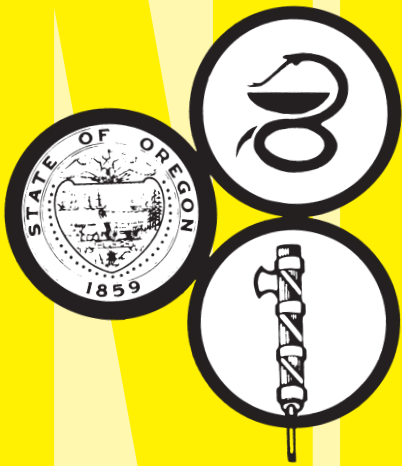


February 2006



NEWS

Oregon State Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

800 NE Oregon St, Room 425
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No. 390: Pharmacy Self-inspection Form

Notice was sent in December 2005 to pharmacies in Oregon indicating that the 2006 pharmacy self-inspection form has been posted on the Oregon State Board of Pharmacy's Web site at www.pharmacy.state.or.us. As a cost saving measure, the Board is asking pharmacists to access and download the form from the Web site. This will eliminate the cost of producing forms and the cost of postage for mailing the form to all pharmacies in the state.

Some chain pharmacists have contacted the Board office to report that their pharmacies are unable to reach the Board's Web site because their access to the Internet is limited, although they do have internal e-mail or other electronic capabilities. Corporate offices for these chains have been contacted by the Board and have agreed to access the form on the Web site and forward it through their internal electronic network, or by e-mail, fax, or mail to their pharmacies. If you are a pharmacist-in-charge (PIC) in an Oregon pharmacy and cannot access the self-inspection form on the Internet, you may contact the Board of Pharmacy office and make arrangements to have a form sent to you.

The self-inspection form is more than just a check list to be completed because it is a requirement. It not only provides questions that the Board believes are important, but it also serves as a reference tool for answers and discussion. It is reviewed and updated annually and reflects the most current thinking of the Board. It can be a valuable tool when incorporated into the orientation and training of pharmacists and other pharmacy staff. The form should be completed every January. Pharmacies may be inspected after February 1, 2006, and the PIC will be expected to produce a completed self-inspection form for the Board's inspector to review.

No. 391: Questions from the Field

The Board's compliance staff receive many questions regarding various aspects of pharmacy practice. Many of these questions do not have an obvious answer and require research or interpretation by the Board. The following is a brief compilation of questions recently discussed by the Board and staff, and the Board's interpretation.

Question: Can a pharmacist supervise two interns where one is working as an intern and the other is working as a technician?

Answer: Yes. By rule, the pharmacist may supervise only one intern. If a second intern is performing technician duties for which he or she has been trained and is not functioning as an intern or performing duties beyond the level of a technician, the pharmacist may supervise both. The second intern cannot function as an intern and a technician at the same time since that would put the pharmacist in the position of supervising two interns at the same time. The second intern may not receive intern hours for functioning as a technician.

Question: In a campus setting, can a pharmacy technician work in one building while being supervised by a pharmacist in another building?

Answer: No. The supervising pharmacist must be in the same building as the technician being supervised. In addition, the supervising pharmacist must know he or she is responsible for supervising that technician, and the technician must know the pharmacist under whose supervision he or she is working. If a technician cannot identify which pharmacist is supervising his or her work, or a pharmacist is unaware that he or she is supervising a technician, the Board may consider that technician as working without supervision.

Question: Can a pharmacist charge a fee for the service of labeling patient samples?

Answer: Yes. A pharmacist may apply a service charge or fee for the service of labeling and handling drug samples or medication assistance program medications. The fee must be a true service charge that is consistent regardless of the published price or cost of the medication. The service charge or fee cannot be based upon or be linked in any way to the value of the medication. Such a variable fee would be considered a dispensing fee and would be a violation of Oregon Revised Statute 689.765(9), which states, "(a) No person may sell, purchase or trade or offer to sell, purchase or trade any drug sample. (b) As used in paragraph (a) of this subsection, 'drug sample' means a unit of a drug, subject to this chapter, that is not intended to be sold and is intended to promote the sale of the drug, and includes a coupon or other form which may be redeemed for a drug."

Question: Can pharmacists receive continuing education (CE) credit for preparing poster presentations?

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.

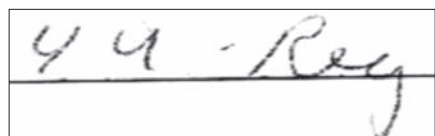
What's wrong with "U"?



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

Answer: Yes. Pharmacists may receive up to two hours of CE credit for a poster (one hour for preparation and one hour for presentation). The Board has not allowed CE credit for attending a poster presentation.

Question: In a hospital pharmacy, is a pharmacist required to check floor stock orders or refill orders for dispensing cabinets (non-patient specific medications) that are filled by a pharmacy technician?

Answer: Yes. All orders including floor stock, restocking for dispensing cabinets, and stock trays (E-kits, anesthesia trays/carts, etc) must be checked and verified by a pharmacist before they leave the pharmacy.

No. 392: Pseudoephedrine Sales Transaction Log

The November 2005 Board of Pharmacy *Newsletter* described the requirement for the Board to adopt rules pursuant to 2005 House Bill (HB) 2485 listing pseudoephedrine (PSE), ephedrine, and phenylpropanolamine (PPA) as Schedule III controlled substances. These rules are being drafted by the Board and will become effective on July 1, 2006. HB-2485 also contained provisions that became effective upon Governor Ted Kulongoski's signature in June 2005 without the need for rule adoption. One such provision is the requirement for pharmacies to make records related to PSE sales available for inspection by the Board and by law enforcement agencies. Another is the requirement that pharmacies provide records to the Oregon State Police (OSP) when directed to do so.

Rules adopted by the Board in May 2005 require pharmacies to maintain a PSE sales transaction log that includes certain specific information about the purchaser. Oregon Administrative Rule 855-050-0038 (3) states, "Any pharmacy that sells [PSE] product must require the purchaser to produce valid photo identification issued by a government or a school before completing the sale and must keep a log, either electronically or by hard copy, of [PSE] sales that contains the following information:

- (a) Purchaser's name;
- (b) A record of the purchaser's form of identification, including:

- (A) Purchaser's driver's license number and state of issue; or
- (B) Purchaser's government or school identification number, if any and date of birth;
- (c) Name or initials identifying the pharmacist or technician who approved the transaction;
- (d) Information reflecting the total milligrams of [PSE] purchased in the transaction . . ."

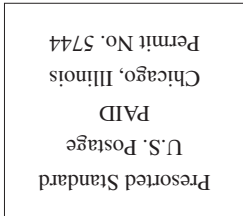
HB-2485 §11(b) states, "Records of transactions involving products containing ephedrine, [PSE] or [PPA] are subject to inspection by the State Board of Pharmacy and law enforcement agencies. A person required to make or maintain records of transactions involving products containing ephedrine, [PSE] or [PPA] shall forward the records to the Department of State Police if directed to do so by the department. Failure to forward records as required by this paragraph is a Class A misdemeanor."

The Department of State Police, in a letter from Lt Michael Dingeman of the OSP Drug Enforcement Section, has issued a request to all Oregon pharmacies to forward their PSE sales logs to the Department. This letter was sent via United States mail to all Oregon Pharmacies on December 23, 2005, and was accompanied by a memo from the Board of Pharmacy. The memo indicated the Board's interpretation that the original PSE sales log may be forwarded to the OSP after copies are made for the pharmacy's records. Accurate copies of the log will be considered in compliance with the Board's recordkeeping requirement and must be maintained on file for two years.

Page 4 – February 2006

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