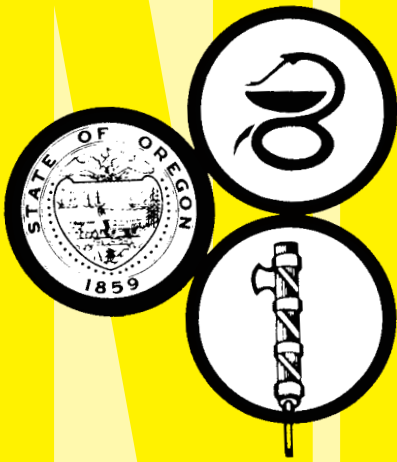


November 2005



Oregon State Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

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No. 386: Pharmacy Services: Considering Moral and Ethical Objections

No provision exists within Oregon pharmacy laws or regulations that requires a pharmacist to dispense every lawful prescription presented in a pharmacy. Indeed, pharmacy laws and regulations require a pharmacist to delay the dispensing of a prescription when faced with questions of potential harm to a patient or concerns of appropriateness of a drug, a dose, or a dosage form for a particular patient. Pharmacists are required to seek clarification prior to dispensing and to collaborate with prescribing practitioners in the patient's best interest.

Just as other health care professionals and practitioners in Oregon have a choice, pharmacists have the right to freely choose whether or not to participate in activities they find morally or ethically objectionable. Oregon pharmacists do not, however, have a right to interfere with a patient's right to receive lawfully and appropriately prescribed drug therapy. The pharmacist has a responsibility to provide professional pharmaceutical care in the patient's interest.

The Oregon State Board of Pharmacy urges each Oregon pharmacy to adopt policies and procedures that address the issues of pharmacists' moral, ethical, and professional rights and responsibilities, and to discuss these with each pharmacist at the time of employment. It is the Board's belief that pharmacy policies and procedures could allow a pharmacist to exercise his or her right not to participate, and at the same time not interfere with the patient's right to receive appropriate and lawful drug therapy. The Board also urges Oregon pharmacists to discuss issues of moral, ethical, and professional rights and responsibilities with their employers.

The Board expects that pharmacy policies and procedures will ensure that patients in Oregon always receive appropriate and lawfully prescribed medications and information in a timely and professional manner and that patients are not burdened by the pharmacist's individual beliefs. Interference with a patient's right to receive timely, professional prescription services and information may be considered unprofessional conduct and could lead to disciplinary action by the Board.

No. 387: Multiple C-II Prescriptions Written at the Same Time

Approximately two years ago, the August 2003 edition of this *Newsletter* contained an article titled "No. 348: Multiple Prescriptions Written at the Same Time." This article incorporated the text of a January 2003 letter written by Patricia Good, chief, Liaison Section, Drug Enforcement Administration (DEA), Office of Diversion Control, to Howard A. Heit, MD. This letter contained the following statements: "The DEA regulations do not prohibit a practitioner from issuing more than one prescription at a time", "... each must bear the actual date that the prescriptions were issued and signed as well as directions for dispensing", "... the prescriptions to be filled at later dates must include directions for the dispensing pharmacist such as, 'Do not dispense before February 2003' and 'Do not dispense before March 9, 2003', and "... the DEA does not consider multiple prescriptions in the scenario outlined above as refills and has authorized this practice provided that it is not a violation of the laws of the state in which the practitioner is licensed."

A November 16, 2004 *Federal Register* notice cast doubt over this practice, by announcing that to do this amounted to "refilling a C-II prescription." The notice went on to assert that the practice is "... a recurring tactic among physicians who seek to avoid detection when dispensing controlled substances [CS] for unlawful purposes."

In a clarification document dated August 19, 2005, Michele M. Leonhart, DEA deputy administrator, stated that, "For a physician to prepare multiple prescriptions [for a Schedule II CS] on the same day with instructions to fill on different dates is tantamount to writing a prescription authorizing refills of a Schedule II [CS]." This statement appears to be a direct contradiction to the message in Patricia Good's letter, and a confirmation of the November 16, 2004 notice.

On January 18, 2005, the DEA published in the *Federal Register* a Solicitation of Comments on the subject of dispensing CSs for the treatment of pain. As noted in the Solicitation, the Administration plans to issue a new *Federal Register* document that will provide a recitation of the pertinent legal

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DEA Amends Rule for Reports of Theft or Significant Loss of Controlled Substances

Drug Enforcement Administration's (DEA) amended regulations regarding reports by registrants of theft or significant loss of controlled substances became effective September 12, 2005. Changes were made to the regulations, found in Title 21 of the Code of Federal Regulations, Part 1300 to 1399, due to confusion as to what constitutes a significant loss and when and how initial notice of a theft or loss should be provided to DEA. Specifically, DEA made changes in order to clarify the exact meaning of the phrases "upon discovery" and "significant loss."

Regarding the timing of initial theft or loss reports, DEA inserted the word "immediately" before the phrase "upon discovery." While DEA Form 106 is not immediately necessary if the registrant needs time to investigate the facts surrounding a theft or significant loss, he or she should provide, in writing, initial notification of the event. This notification may be a short statement provided by fax. DEA notes that faxing is not the only method a registrant may use, but that the notification should be in writing. If the investigation of a theft or significant loss lasts longer than two months, registrants should provide updates to DEA.

To help registrants determine whether or not a loss is "significant," DEA has added to the rule a list of factors to be considered. DEA recognizes that no single objective standard can be applied to all registrants – what constitutes a significant loss for one registrant may be construed as comparatively insignificant for another. If a registrant is in doubt as to whether or not the loss is significant, DEA advises the registrant to err on the side of caution in alerting the appropriate law enforcement authorities.

Regarding "in-transit losses of controlled substance," DEA intends that all in-transit losses be reported, not just significant losses; therefore, the text is being amended to reflect this.

Changes to the regulations were reported in the August 12, 2005 edition of the *Federal Register*.

FDA Releases Update on Combating Counterfeit Drugs

Food and Drug Administration (FDA) recently released "Combating Counterfeit Drugs: A Report of the Food and Drug Administration Annual Update (Update)." This Update follows up on the agency's initial February 18, 2004 report addressing counterfeit drugs. Since the 2004 report, which identified measures that can be taken to better protect Americans from counterfeit drugs, FDA has worked with manufacturers, wholesale distributors, pharmacies, consumer groups, technology specialists, standard setting bodies, State and Federal agencies,

international governmental entities, and others to advance the measures outlined in the 2004 report such as the development and implementation of electronic product codes and radio frequency identification. In its 2005 Update, FDA notes that significant progress is being made in securing drug products and packaging, securing the movement of the product, enhancing regulatory oversight, increasing penalties for counterfeiters, heightened vigilance and awareness of counterfeits, and increasing international collaboration. However, more work needs to be done to further secure the United States' drug supply.

In 2004, FDA's Office of Criminal Investigations initiated 58 counterfeit drug cases, a significant increase over the 30 cases in 2003; however, the agency notes that this is likely due to increased vigilance. FDA also states that most of the suspect counterfeits discovered in 2004 were found in smaller quantities than those found in 2003.

The Update reviews steps taken and future actions required for track-and-trace technology, authentication technology, regulatory oversight and enforcement (electronic pedigree), state efforts, secure business practices, heightened vigilance and awareness, counterfeit alert network, and education. The full Update can be accessed at www.fda.gov/oc/initiatives/counterfeit/update2005.html.

"Fax noise" = Medication Errors in the making



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, Suite 810, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Problem: Most health care practitioners would agree that fax machines have facilitated communication of prescriptions. But there are inherent problems associated with this technology. In fact, an article in the *Journal of Managed Care Pharmacy* found that prescriptions received by fax required a greater number of clarification calls than those received by other methods of communication.¹ ISMP received a report from a long-term care facility about a patient who had been

Compliance News

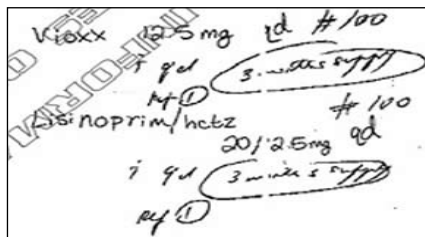
Compliance News to a particular state or jurisdiction should not be assumed. The law of such state or jurisdiction.)



receiving **Neurontin**[®] (gabapentin) 600 mg TID [three times a day]. However, an order had been faxed to the pharmacy to change the Neurontin dose to “**300 mg** 1 tab QID [four times a day].” The change was made and the new dose was sent to the facility. Later, when the pharmacist received the original order from the long-term care facility and compared it with the faxed copy, he realized that the physician had actually requested a change to “**800 mg** 1 tab QID.” The left side of the order had been cut off during the fax transmission, making the “8” look like a “3.” Fortunately, since the pharmacist had been sent the original order for comparison, he quickly realized the mistake. Unfortunately, not all pharmacies receive the original prescription for comparison purposes.

In another report received by ISMP, a faxed prescription was received at a pharmacy for what appeared to be **Monopril**[®] (fosinopril) **10 mg** #90 one tablet daily. Despite the fact that the fax machine created a definite vertical streak that ran between the drug name and the strength, the pharmacist felt confident in her interpretation of the prescription. Unfortunately, it was later discovered that the prescription was actually for **40 mg**. The streak had run through the “4” in 40 mg, making it look like 10 mg instead.

The following prescription (see image below) was faxed to a mail-order pharmacy. Look at the bottom order for “Lisinopril/hctz.” (Note: ISMP does not condone the use of the abbreviation “hctz.”) The pharmacist interpreted this order as “20/25 mg.” But what the prescriber had actually written was “20/12.5 mg.” A subtle vertical gap in the faxed copy (which can be seen “breaking” the circles around “3 months supply”) had obliterated the “1” in 12.5. In addition, the pharmacist reading the order had mis-



interpreted the decimal point as one of many stray marks on the faxed prescription.

Safe Practice Recommendations: “Fax noise” (the random marks and streaks on faxes) is an inherent problem with this form of communication, which may be more common in old or poorly maintained fax machines. Usually, fax noise is just an inconvenience. In the case of prescriptions, however, there is a very real chance that a patient could be harmed by misinterpretations caused by fax noise. To manage this risk, safeguards should be instilled into the fax process. Such safeguards include a careful review of all prescriptions received by fax for fax noise. If the transmission has fax noise in the area of the order, the prescriber should be contacted to confirm the prescription. Whenever pos-

sible, compare the faxed order against the original prescription. Prescribers should consider giving a copy of the prescription to the patient to present at the pharmacy for verification. To prevent confusion or duplication of the prescription at a different pharmacy, the copy could be stamped with a statement such as “Verification Copy ONLY” to indicate that the prescription was already faxed to a particular pharmacy. Maintenance should be regularly scheduled for fax machines on both the sending and receiving end. If maintenance fails to improve fax quality, the machine should be replaced.

¹ Feifer RA et al. Mail-order prescriptions requiring clarification contact with the prescriber: prevalence, reasons, and implications. *JMCP* 2003;9:346-352.

December 2005 FPGEE Date and Locations Announced

On December 3, 2005, NABP will again administer a paper-and-pencil Foreign Pharmacy Graduate Equivalency Examination[®] (FPGEE[®]). The examination is being offered at three United States locations: Northlake (Chicago area), IL; New York, NY; and San Francisco, CA. Candidates who have been accepted to sit for the December 3, 2005 administration were mailed their admission tickets in early fall.

To prepare for the December examination, candidates may take the Pre-FPGEE[®], a Web-based practice examination for the FPGEE. The practice examination is accessible at www.nabp.net and www.pre-fpgee.com.

For more information on the FPGEE, visit NABP’s Web site at www.nabp.net.

2006 Survey of Pharmacy Law

NABP’s *2006 Survey of Pharmacy Law* CD-ROM will be available in late November 2005. New topics include the number of wholesale drug distributors and laws and/or regulations concerning the sales of over-the-counter pseudoephedrine, and information concerning emergency contraception.

The *Survey* consists of four sections: organizational law, licensing law, drug law, and census data. Most charts specify terms that can be used when conducting searches on NABP’s NABPLAW[®] Online state pharmacy law and rules database. The *Survey* can be obtained for \$20 from NABP by downloading the publication order form from www.nabp.net and mailing in the form and a money order to NABP. The CD-ROM is provided free of charge to all final-year pharmacy students through a grant from AstraZeneca Pharmaceuticals. If you do not have Web access or would like more information on the *Survey*, please contact NABP at 847/391-4406 or via e-mail at custserv@nabp.net.

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principles relating to the dispensing of CSs for the treatment of pain. As of this printing, that document has not been released and no timeline for its release has been offered.

Issuing multiple prescriptions for C-II CSs with instructions to dispense at a later date is not a violation of Oregon pharmacy laws and rules, and the Board continues to accept the procedure as described in the January 2003 letter. However, violation of federal drug laws is a violation of the Oregon Pharmacy Act. If DEA begins to enforce its current position and a pharmacist were to be prosecuted for violations of the Federal Controlled Substances Act, the Board could be forced to take action.

No. 388: Upcoming Board Member Position

In June 2006, pharmacist and veteran Board of Pharmacy member Blake Rice completes his second and final term on the Board. The Governor's office is reviewing existing applications and accepting new letters of interest from pharmacists to fill the upcoming vacancy. If you are interested or know someone who may be interested in serving on the Board, you can contact the Oregon State Pharmacy Association via its Web site at www.oregonpharmacy.com to discuss its process for making recommendations. As an alternative, you may contact the Governor's Office for Executive Appointments directly. A form including detailed instructions for expressing interest in a Board position can be downloaded from the Governor's Web site at www.governor.oregon.gov/Gov/boards.shtml#Executive_Appointments.

No. 389: Oregon's Pseudoephedrine Status

Methamphetamine (meth) and its primary precursor, pseudoephedrine (PSE) has received more than its share of notoriety and more than its share of attention from the Governor, the Board, and the Legislature over the past year. The Governor met with the Board on several occasions, the Board adopted emergency temporary rules and permanent rules restricting the sale of PSE, and Board members and staff appeared before legislative committees throughout the 2005 legislative session.

This article is an attempt to clarify the current status of the Board's PSE related activities.

With the passage of Senate Bill 2485, the legislature removed the existing exemption enjoyed by PSE from its C-II scheduling under the Oregon Uniform Controlled Substances Act and required the Board to change the schedule of PSE from C-II to C-III. The legislature further authorized the Board to evaluate the impact of this scheduling change over time and to further adjust PSE's schedule if it finds that restrictions under the C-III status do not continue to reduce the number of meth labs in Oregon.

The Board has established a Rules Advisory Committee and is in the process of researching the rule writing requirements and the details around the status of substances that are controlled under state law and not under federal law. This includes security and transportation requirements at the wholesale level as well as security, labeling, and recordkeeping requirements in the pharmacy.

The Board will have to adopt rules before PSE becomes a C-III. The Board believes that the rules will not be difficult to write once the logistical details are understood. A working draft will be developed by staff and reviewed by the Advisory Committee. A fiscal impact statement will be developed and public hearings will be held pursuant to the State's required rule making process. Until this process is completed, the status of PSE remains under the existing permanent rules, which are described in the May 2005 edition of this *Newsletter*.

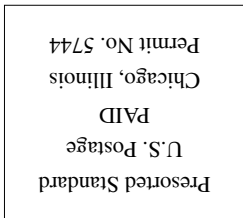
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