

Montana Board of Pharmacy

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Drug Enforcement Administration Schedule II Controlled Substance Policy:

On August 26, 2005, the Drug Enforcement Administration (DEA) published the following clarifications in the *Federal Register* regarding the writing and filling of Schedule II controlled substances (CS):

1. As the Interim Policy Statement states, "For a physician to prepare multiple prescriptions [for a Schedule II controlled substance] on the same day with instructions to fill on different dates is tantamount to writing a prescription authorizing refills of a Schedule II controlled substance." To do so conflicts with the provision of the CSA [Controlled Substance Authority] which provides: "No prescription for a controlled substance in Schedule II may be refilled."
2. Many of the comments that DEA received were from patients who said they have been receiving prescriptions for Schedule II controlled substances for several years (for example, for the treatment of severe pain or attention deficit hyperactivity disorder) and have gotten into a routine of seeing their physician once every three months. Many such commenters were under the mistaken impression that, because of the Interim Policy Statement, they now must begin seeing their physician every month. DEA wishes to make clear that the Interim Policy did not state that such patients must visit their physician's office every month to pick up a new prescription. There is no such requirement in the CSA or DEA regulations. What is required, in each instance where a physician issues a prescription for any controlled substance, is that the physician properly determine there is a legitimate medical purpose for the patient to be prescribed that controlled substance and that the physician be acting in the usual course of professional practice. **21 CFR 1306.04 (a)**.

At the same time, Schedule II controlled substances, by definition, have the highest potential for abuse, and are the most likely to cause dependence, of all the controlled substances that have an approved medical use. **21 U.S.C.812 (b)**. Physicians must, therefore, use the utmost care in determining whether their patients for whom they are prescribing Schedule II controlled substances should be seen in person each time a prescription is issued or

whether seeing the patient in person at somewhat less frequent intervals is consistent with sound medical practice and appropriate safeguards against diversion and misuse. Physicians must also abide by any requirements imposed by their state medical boards with respect to proper prescribing practices and what constitutes a bona fide physician-patient relationship. **21 U.S.C. 823 (f) (1), (4)**.

3. Under the circumstances described in paragraph 2, in those instances where the physician (who regularly sees a patient) issues a prescription for a Schedule II controlled substance for a legitimate medical purpose without seeing the patient in person, the physician may mail the prescription to the patient or pharmacy. In addition, as DEA regulations state: "A prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy via facsimile equipment, provided that the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except as noted [elsewhere in this section of the regulations]. **21 CFR 1306.11(a)**. Thus, as this provision of the regulations provides, faxing may be used to facilitate the filling of a Schedule II prescription, but only if the pharmacy receives the original written, signed prescription prior to dispensing the drug to the patient.
4. The CSA and DEA regulations contain no specific limit on the number of days worth of a Schedule II controlled substance that a physician may authorize per prescription. Some states, however, do impose specific limits on the amount of a Schedule II controlled substance that may be prescribed. Any limitations imposed by state law apply in addition to the corresponding requirements under federal law, so long as the state requirements do not conflict with or contravene the Federal requirements. **21 U.S.C. 903**. Again, the essential requirement under Federal law is that the prescription for a controlled substance be issued for a legitimate medical purpose in the usual course of professional practice. In addition, physicians and pharmacies have a duty as DEA registrants to ensure that their prescribing and dispensing of controlled substances occur in a manner consistent with effective controls against diversion and misuse, taking into account the nature of the drug being prescribed. **21 U.S.C. 823 (f)**.

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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

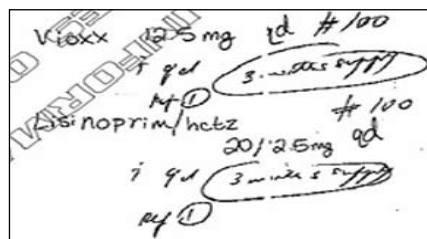
Compliance News to a particular state or jurisdiction should not be assumed (the law of such state or jurisdiction.)



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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While it is **no longer acceptable** to write **or fill** multiple prescriptions for the same patient and same medication on the same day with a notation “do not fill before ___”, DEA acknowledges that written prescriptions for Schedule II CS can still be mailed to patients and that federal law does not limit the quantity of medication per prescription. Montana law likewise gives no quantity limitation, but third party carriers and the financial status of the patient often serve as limiting factors. Our Board is disappointed in the position taken by DEA, and feels that any policy that could cause or encourage prescribers to write for larger quantities of CS could potentially increase the loss and diversion of these drugs. Nevertheless, this is DEA’s current position and by default it is ours as well. The Board reminds you that **all** prescriptions must be dated as of the date on which they are written. It is **never** legal to post-date a prescription.

Emergency Room Dispensing

It is in the best interest of the patient to begin many medications at the time of an emergency room (ER) visit. Many acute care facilities in Montana do not have nighttime and/or weekend pharmacy coverage. Pharmacists responsible for medication provision in such facilities should develop a list of potential take-home medications in collaboration with their P&T or other appropriate committee, and the pharmacist should pre-package and properly label the medications for potential emergency use, placing them in moisture- and light-resistant childproof containers with expiration date noted. Antibiotics to be reconstituted can be packaged together with a labeled bottle containing the correct amount of water and instructions for reconstitution.

Four years ago, the Boards of Medical Examiners, Nursing, and Pharmacy agreed that no violation of rule or statute occurs when an on-site licensed practitioner **with prescriptive authority** gives a licensed nurse an order to issue pre-packaged, properly labeled medications to a patient registered in the ER for home use **when no pharmacy within a 10-mile radius is open and no staff pharmacist is on duty**. Practitioners **with prescriptive authority** are permitted to dispense drugs in an emergency setting, and may package and label medications for a licensed nurse to hand to a patient under these circumstances.

As long as the nurse is **not** the person who packages and labels the drug for the patient, he or she is in compliance with all applicable statutes and rules. The boards of nursing and pharmacy wish to emphasize that **a licensed ER nurse may not prepare and dispense medications to a patient pursuant to an after-hours phone call from an off-site practitioner.**

An Up-to-Date Check on Prescriptive Authority

Current licensure status for physicians and others with prescriptive authority can be found at www.discoveringmontana.com/dli/bsd or by calling Evie Martin at 406/841-2364. For DEA registration queries call 303/705-7300 or 1-800/882-9539.

To Everything There is a Season

It is with mixed feelings and a little sadness that I will leave the position of executive director this month to return to the practice of pharmacy. It has been a privilege to work with the dedicated members of the Board and help them update pharmacy rules to adequately address current pharmacy issues. It has also been a pleasure to work with so many fine practitioners across our state and be reminded of the many reasons I entered our profession so many years ago. That profession continues to evolve in exciting new ways. Thanks for the many caring ways in which you have gone the extra mile to touch your patients’ lives and my life as well. Be well, do good work, and keep in touch.

Becky Deschamps

Board of Pharmacy October Meeting

The Board of Pharmacy will meet October 13-14 in Missoula. Call 406/841-2355 or visit www.discoveringmontana.com/dli/pha for more information.

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