



# Minnesota Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

## ***Disciplinary Activity***

During the months of June, July, and August, the Minnesota Board of Pharmacy completed the disciplinary process on the following disciplinary case:

**Ramler, Marlin M., License No. 109851-6.** Subsequent to a conference held with Mr Ramler to discuss allegations of unprofessional conduct, Mr Ramler agreed to permanently surrender his license to practice pharmacy in Minnesota.

## ***Rule-Making Process Continuing***

Since the last *Newsletter*, Board staff has continued its work on developing a package of proposed rule changes that will be officially proposed in the fall.

Pharmacy Board Surveyor Michele Mattila has convened an ad hoc committee of practicing pharmacists to participate in developing rule changes that would primarily impact community pharmacies. The community pharmacy group has met on three different occasions as of the end of August 2005, and is nearing completion of its work.

Similarly, Pharmacy Board Surveyor Candice Fleming has convened another ad hoc committee composed primarily of institutional pharmacists who have been developing the language for proposed rule changes affecting primarily institutional practice. Their work is also nearing completion.

When the ad hoc advisory committees have completed their work, the two packages of proposed rule change language will be merged into one document and recirculated to each of the committees. The proposed rule package will then be started on its lengthy passage through the formal rule-making process. Future copies of this *Newsletter* will be used to keep Minnesota pharmacists informed of the rule-making proposals as they make their way through the process.

## ***High Numbers of New Licensees Continues***

During the past three months, June, July, and August of 2005, the Board has granted licensure to 157 full Board examination candidates for licensure and an additional 25 individuals who obtained licensure by reciprocity.

While the number of full Board examination candidates appears, on the surface, to be down from the previous two

years, it must be remembered that candidates now must sit for the licensing examinations, both the North American Pharmacists Licensure Examination™ and the Multistate Pharmacist Jurisprudence Examination®, on their own schedule and it is anticipated that there are still a fair number of candidates who intend to obtain licensure in Minnesota who have not yet completed the examination process.

As is typically the case, examination performance by new graduates from the University of Minnesota and the other schools of pharmacy in the upper Midwest continues to demonstrate the excellence of the education of these students. Performance by the candidates for licensure for the state of Minnesota is well above the national average.

## ***Board Continues to Work Toward Online License Renewals and Online License Verifications***

While progress has been slow at times, Board staff is continuing to work with licensing system software developers to upgrade the Board's current licensing program that when the upgrade is completed, will allow the Board to implement online license renewals for the various licensees and will allow employers to go online to verify the license status of pharmacists, technicians, and interns. It is hoped that the new licensing system will be in place prior to the next license renewal cycle.

Additional information on the upgraded licensing system will be available in future *Newsletters*.

## ***Continuing Education Checkup***

The two-year continuing education (CE) reporting cycle is now approximately half over. Minnesota pharmacists are encouraged to review their progress in obtaining their 30 hours of CE participation that will need to be reported at the end of September 2006.

Among the changes included in the previously discussed package of rule changes are two different changes that involve CE. First, the Board is proposing to waive CE participation for any Minnesota pharmacists who are members of the National Guard or other armed forces that may be called to active duty outside of the United States. In such a case, the Board is

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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](http://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](http://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](mailto:ismpinfo@ismp.org).*

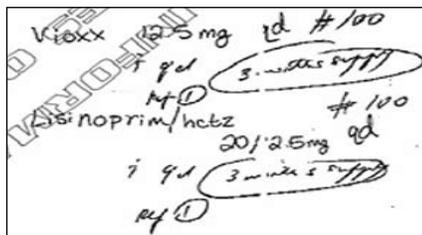
**Problem:** Most health care practitioners would agree that fax machines have facilitated communication of prescriptions. But there are inherent problems associated with this technology. In fact, an article in the *Journal of Managed Care Pharmacy* found that prescriptions received by fax required a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



receiving **Neurontin**<sup>®</sup> (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**<sup>®</sup> (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.

<sup>1</sup> 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<sup>®</sup> (FPGEE<sup>®</sup>). 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<sup>®</sup>, a Web-based practice examination for the FPGEE. The practice examination is accessible at [www.nabp.net](http://www.nabp.net) and [www.pre-fpgee.com](http://www.pre-fpgee.com).

For more information on the FPGEE, visit NABP’s Web site at [www.nabp.net](http://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<sup>®</sup> 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](http://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](mailto:custserv@nabp.net).

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proposing that the CE requirement would be waived until the individual returns to the US where CE programming is more readily available.

The second proposed change relating to CE is that any request for an extension of time in which to complete the CE requirement will need to be accompanied by a late performance fee of \$100.

Pharmacists who delay completing their CE requirement end up generating a significant amount of staff time and record keeping at the Board office. The Board hopes that attaching a \$100 fee for late reporting of CE participation will encourage pharmacists to get their CE completed in a timely manner and will help reduce the burden on Board staff in tracking those late reporting pharmacists.

### **Address Change Notification Essential**

Minnesota pharmacists and pharmacy technicians are reminded to keep the Board informed of any changes to their mailing address. License renewal applications for both pharmacists and technicians are sent to the address currently recorded in the Board's computer system.

In the case of pharmacy technicians, it has been noticed that a number of technicians use their place of employment as the mailing address for the Board of Pharmacy. When these individuals leave employment or change their place of employment, they often forget to notify the Board of a new address and, as a result, the individuals are often delayed in receiving the renewal application. Generally pharmacists are somewhat better at keeping the Board informed of their current mailing address, but every year during license renewal time the Board receives dozens of renewals returned when the individual has moved and is no longer at the address listed with the Board.

Please be sure to keep the Board informed of an accurate mailing address at all times.

### **Retirement**

*David E. Holmstrom, JD, RPh, Executive Director, Minnesota Board of Pharmacy*

I retired from my position as executive director of the Minnesota Board of Pharmacy on September 20, 2005.

Over the many years that I wrote this *Newsletter*, it was my intention to attempt to keep the lines of communication between the Board and Minnesota pharmacists open, and to provide pharmacists with information they will be able to use in their day-to-day practice.

Over the years there have been times when I have struggled to appropriately fill the four pages of the *Newsletter* and there have been other times when four pages, or even double that amount, seemed insufficient.

I have thoroughly enjoyed the opportunity that I have had to communicate with virtually all the pharmacists of the state of Minnesota and to get to know many of you personally. I will certainly miss that opportunity to be part of your professional lives.

On the other hand, I look forward to many new adventures unburdened by the need to report to work on a daily basis and to be in a position to do a little fishing, play a little golf, and totally ignore snarled up rush-hour traffic on snowy days in the Twin Cities.

At the September 14, 2005 meeting the Board of Pharmacy officially appointed Mr Cody Wiberg as my replacement.

Cody is a PharmD graduate of the University of Minnesota and most recently held the position of director of pharmacy programs for the Minnesota Department of Human Services.

Cody has indicated that he looks forward to interacting with the pharmacy profession in a more positive manner than was possible in his previous position and looks forward to protecting the public health from a somewhat different perspective.

I sincerely trust that the warm welcome I have so appreciated over the many years will be extended to Cody also.

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