October 2006

Minnesota Board of Pharmacy

University Park Plaza
2829 University Ave SE, Suite 530
Minneapolis, MN 55414-3251
www.phcybrd.state.mn.us

Published to promote voluntary compliance of pharmacy and drug law.

Board Operations

As mentioned in the last *Newsletter,* the state of Minnesota is converting agencies to a new phone system based on a voice-over-Internet protocol (VoIP). The Minnesota Board of Pharmacy now has a VoIP system in place. The most notable change for Board customers is a voice menuing system. Individuals calling the Board's main phone number now select from menu options so that their calls can be better routed to the appropriate staff. **The Board's new main phone number is 651/201-2825 and the fax number is 651/201-2837.**

Disciplinary Activity

The Board completed the following disciplinary actions concerning **pharmacists** between the dates of June 1, 2006 and August 31, 2006.

Boos, Jodi A., License #114230. Ms Boos admitted to the theft of controlled substances (CS) from her employer and the unauthorized personal use of those drugs. She was placed on probation until December 31, 2009, or until successful completion of a participation agreement with the Health Professionals Services Program (HPSP).

Benassi, John A., License #111836. It was alleged that Mr Benassi knowingly filled an invalid prescription and that he deliberately failed to inform the Board of his participation in HPSP when applying to have his pharmacy license reinstated. He was placed on probation, subject to certain conditions, until he successfully completes a participation agreement with HPSP.

Kohs, Gordon L., License #113295. Mr Kohs successfully completed his probation, and the Board granted his petition for an unrestricted license.

O'Rourke, Kevin J., License #118173. Mr O'Rourke admitted to violating state laws regulating the dispensing of CS. He agreed to voluntarily and permanently surrender his license to practice as a pharmacist in the state of Minnesota.

Ploszay, Thomas M., #112617. Mr Ploszay admitted to several practice-related deficiencies, which resulted in a number of dispensing errors. He was placed on probation, subject to certain conditions, for two years. Mr Ploszay may petition the Board to have his probation lifted after the first year.

Governor Makes Board Appointments

During June of 2006, Governor Tim Pawlenty announced appointments for the two Board positions that had technically expired on the first Monday in January 2006. Board member **Gary Schneider**, a pharmacist from Plymouth, MN, was reappointed to a second four-year term. Mr Schneider is the vice president of Gallipot, a pharmaceutical manufacturer located in Mendota Heights, MN. He served as the Board's president in 2005 and is a former Board chair and president of the Minnesota Pharmacists Association.

Ikram-Ul-Huq was appointed as a public member to fill the position that has been vacant since Jean Lemberg passed away last year. He received a master of arts degree in economics from Texas Tech University in Lubbock, TX. Mr Huq lives in Apple Valley, MN, and works for General Motors Acceptance Corporation-Residential Funding Corporation (GMAC-RFC) in Bloomington, MN. In the past, Mr Huq worked for the United Nations Children's Fund (UNICEF) in Iperu, Nigeria. A former professional cricket player, he currently serves as president of the Cosmos Cricket Club in Minnesota. Mr Huq serves as Imam at the Masjid Ar Rehman and is a founding member and religious director of the Muslim Community Center in Bloomington.

The terms of both of these members will expire on the first Monday in January 2010.

Continuing Education

Minnesota pharmacists are reminded, by the time this edition is published, they should have completed their required 30 hours of continuing education (CE) for the period from October 1, 2004 to September 30, 2006. The Certificate of Completion, which was previously mailed to all pharmacists, should have been signed, dated, and returned to the Board of Pharmacy office prior to October 1, 2006. Pharmacists who have not returned their Certificate of Completion will not receive a renewal notice next year – unless they have been granted an extension by the Board.

Randomly selected pharmacists will be asked to submit documentation that verifies their completion of 30 hours of CE during the period mentioned above. Audit notices will be sent out by the end of November. Pharmacists who have not received a notice by then can assume they will not be audited for the reporting period that has just ended.

Pharmacists-in-Charge

Minnesota rules require a pharmacist to notify the Board immediately upon receiving knowledge that his or her service as a pharmacist-in-charge (PIC) has been or will be terminated.

Continued on page 4

FDA Launches Consumer Educational Program on the Safe Use of OTCs

The United States Food and Drug Administration's (FDA) Center for Drug Evaluation and Research, in cooperation with the National Council on Patient Information and Education and Maryland's Montgomery County Public Schools, has launched "Medicines in My Home," an interactive educational program aimed at informing middle school students about the safe and effective use of over-the-counter (OTC) medicines. Key concepts students will learn from the program are:

- the Drug Facts label tells you what a medicine treats, if it is right for you and your problem, and how to use the medicine;
- read the label and follow the directions carefully and correctly;
- two medicines with the same active ingredient should not be used at the same time; and
- measure medicines correctly with measuring tools made for medicines.

The program emphasizes that medicines should be used only with permission from an adult and that if there are questions about medicine use, ask a pharmacist or doctor. Materials are provided to encourage students to share what they learn with their families so that all family members can learn to use OTC medicines more safely. Program information can be found at www.fda.gov/medsinmyhome.

HHS Warns Public of Heroin and Fentanyl Deadly Combo

In efforts to warn the public and health care professional communities regarding a recent rash of drug-related deaths due to an illicit street drug combination consisting of the prescription medication fentanyl and either heroin or cocaine, the Department of Health and Human Services (HHS) released a fact sheet containing specific information with the goal of saving lives.

A letter from H. Westley Clark, director of HHS Center for Substance Abuse Treatment, to health care professionals warned that in "just one week, an estimated 33 individuals in the Detroit, MI area are reported to have died after using this fatal mix of drugs; the same drug combination may have been responsible for more than 100 deaths in the same region last September [2005]." Philadelphia, PA; Chicago, IL; St Louis, MO; and Camden, NJ have also recently experienced similar clusters of drug-related deaths.

Fentanyl, an injectable Schedule II prescription opioid analgesic, is roughly 50 to 80 times more potent than morphine but can also be produced in clandestine laboratories in powder form and then mixed with or substituted for heroin. Fentanyl-related overdoses can result in sudden death through respiratory arrest, cardiac arrest, severe respiratory depression, cardiovascular collapse, or severe anaphylactic reaction. In some cases, heroin or cocaine users are aware they are purchasing this dangerous combination of drugs and in other cases, they are not. Because the potency of street-sold heroin or cocaine is amplified markedly by fentanyl and because the inclusion of fentanyl may not be disclosed, any use, even a reduced dose, can result in overdose or death. The fact sheet advises that suspected overdoses should be treated rapidly with a naloxone injection, 0.4 to 2 mg intravenously, subcutaneously, or intramuscularly every two to three minutes, which should rapidly reverse symptoms related to a narcotic overdose; if there is no response after 10 minutes, then a different diagnosis should be considered.

For additional information, contact Kenneth Hoffman at the Substance Abuse and Mental Health Services Administration at 240/276-2701 or via e-mail at Kenneth.Hoffman@samhsa.hhs.gov.

Pharmacy Technicians and Medication Error Prevention

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

In an October 2005 article in the *American Journal of Health-System Pharmacists*, the results of a random nationwide survey of more than 800 pharmacy technicians' views about their medication errors was published (Desselle SP. Certified pharmacy technicians' views of their medication preparation errors and educational needs. *Am J Health-Syst Pharm.* October 1, 2005; 62:1992-97). Most of the technicians worked in community pharmacies, but more than a quarter (27%) were employed in hospitals.

As one might expect in both settings, interruptions and inadequate staffing were among the most frequent factors perceived to contribute to technician medication preparation errors. Inadequate staffing was perceived as especially problematic in chain pharmacies, while inadequate supervision by pharmacists was cited as a factor more frequently by hospital technicians. It also may come as no surprise that the pharmacists' most frequently cited response to an error that was caught during the checking process was to make the technician aware of the error and require him or her to correct it. However, only about 17% of the technicians reported that the pharmacist had used the error as an opportunity to provide instructions on how to avoid the same or similar errors in the future.

While many of these respondents attributed this responsibility to the organization as a whole, not necessarily the individual pharmacist who detects an error, it appears technicians may not be receiving guidance about system and process changes that can help avert errors. After an

error is corrected, the checking pharmacist should find time that same day (or the next day, if necessary) to review the error with the technician and suggest ways to avoid it, including safer behavioral choices if applicable. Later, during pharmacy staff meetings or other forms of intradepartmental communication, errors, their causes, and ways to prevent them should be shared with all staff in a way that does not embarrass those who were possibly involved in the errors.

One or Both Nostrils?

Submitted by ISMP

Although many nasal sprays are intended for administration in each nostril for a single dose, there are notable exceptions. For example, some medications are meant to be delivered via the nasal passage but **not** sprayed into each nostril. Calcitonin salmon (**Fortical®, Micalcin®**) is a prime example. Patients should administer a single spray (200 international units) into one nostril daily, using alternate nostrils each day. Other examples in metered-dose or unit-dose nasal spray containers include butorphanol, desmopressin (**DDAVP®**), sumatriptan (**Imitrex®**), and zolmitriptan (**Zomig®**).

Some pharmacy and/or physician electronic prescribing systems have been preprogrammed to print directions that default to "spray in each nostril" when nasal sprays are selected. For the previously mentioned drugs, this would result in the administration of a double dose of medication. One health care facility recently reported that about 50 patients, who had been prescribed medications intended to be given into one nostril, had prescription container labels that instructed the patients to administer the spray into both nostrils. Some physicians might anticipate patients' confusion and write the prescription for "half" doses in each nostril. Even if instructed to use the spray in one nostril, patients who administer other nasal medications in both nostrils may spray these medications into both nostrils without thinking.

Explicit verbal directions and written instructions that emphasize administration via one nostril only are critical to avoid an overdose.

FDA/ISMP National Campaign to Help Eliminate Ambiguous Medical Abbreviations

FDA and the ISMP have launched a national education campaign that focuses on eliminating the use of potentially harmful abbreviations by health care professionals, medical students, medical writers, and the pharmaceutical industry. The campaign addresses the use of error-prone abbreviations in all forms of medical communication, including written medication orders, computer-generated labels, medication administration records, pharmacy or prescriber computer order entry screens, and commercial medication labeling, packaging, and advertising. For more information visit www.fda.gov/cder/drug/MedErrors.

DEA Provides Retail Training Materials

Drug Enforcement Administration (DEA) recently announced the availability of training materials regarding self-certification training for regulated retail sellers of non-prescription drug products containing ephedrine, pseudoephedrine, and phenylpropanolamine as required by the Combat Methamphetamine Epidemic Act of 2005 (Title VII of Public Law 109-177).

Two sets of training materials have been developed: one for regulated persons who are mobile retail vendors, and one for regulated persons who are not mobile retail vendors. Both sets of training materials may be found on the Diversion Control Program Web site, www.deadiversion.usdoj.gov, under "Combat Methamphetamine Epidemic Act of 2005."

DEA notes that regulated sellers must use the content of these training materials in the training of their employees who sell scheduled listed chemical products. A regulated seller may utilize additional content in its training program, but DEA's posted material must be included.

DEA is continuing to work to promulgate regulations to implement the Combat Methamphetamine Epidemic Act of 2005.

FDA Announces Release of Guidance on Useful Written Consumer Medication Information

In the July 18, 2006 *Federal Register,* FDA announced the availability of a guidance entitled "Useful Written Consumer Medication Information (CMI)." This guidance is intended to assist individuals or organizations (eg, pharmacies, private vendors, health care associations) in developing useful written consumer medication information to comply with Public Law 104-180. CMI is written information about prescription drugs developed by organizations or individuals, other than a drug's manufacturer, that is intended for distribution to consumers at the time of dispensing. Since neither FDA nor the drug's manufacturer reviews or approves CMI, FDA recommends that the developers of written medication information use the factors discussed in this guidance to help ensure that their CMI is useful to consumers.

This guidance can be accessed at www.fda.gov/cder/guidance/7139fnl.htm.

2007 Survey of Pharmacy Law Available Soon

NABP's 2007 *Survey of Pharmacy Law* CD-ROM will be available in early December 2006. New topics include whether or not licensure for wholesale distributors of non-prescription drugs is required and the recognition of Verified-Accredited Wholesale Distributors™ accreditation.

The *Survey* consists of four sections: organizational law, licensing law, drug law, and census data. 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.

Continued from page 1

In addition, each pharmacy is required to notify the Board of the termination of the service of a PIC, immediately designate a successor PIC, and immediately notify the Board of the designation. It has come to the Board's attention that some pharmacies have gone without a PIC for several months because no successor was named for a departing PIC.

Proposed Rules Package

The Board of Pharmacy has been working to update Board rules in many different areas including: definitions, license categories, pharmacy satellites, patient access to pharmacists, closure of a pharmacy, required reference books and equipment, applications for licensure, reciprocal licensure, drug manufacturer or wholesaler licensure, pharmaceutical waste, vending machines, return of drugs and devices, prescription numbers, electronic prescriptions, compounding and dispensing, transfer of prescriptions between pharmacies, prepackaging and labeling, pharmacy compounding practices, beyond-use dates, prescription labeling, labeling of outpatient intravenous admixture drugs, electronic data processing, Schedule III and V CS, registration of CS researchers, CS samples, prescription order communication, hospital PIC, patient care, pharmaceutical services policies, policy and procedure manuals, physical requirements, service and filing of papers, variances, registration of medical gas retailers, and continuing pharmaceutical education.

By the time this edition is published, a Notice of Intent to Adopt Rules will have been published in the *Minnesota State Register*. Depending on the date of publication of the notice, there may still be an opportunity for members of the public to submit written comments on the proposed rules or written requests that a hearing be held. If 25 or more persons submit a written request for a hearing, a public hearing will be held. The Board anticipates final adoption of the proposed rules by the end of this year.

The proposed rule changes are available for viewing on the Board's Web site. Copies can also be obtained by contacting the Board of Pharmacy office. Interested persons are encouraged to review and provide comment on the proposed rule changes.

Provider Cost Disclosure

The Board is required by law to remind pharmacists that they must make certain price disclosures to their patients. Specifically, pharmacists must comply with Minnesota Statute 151.214, which states:

"Subdivision [Subd.] 1. Explanation of pharmacy benefits. A pharmacist licensed under this chapter must provide to a patient, for each prescription dispensed where part or all of the cost of the prescription is being paid or reimbursed by an employer-sponsored plan or health plan company, or its contracted pharmacy benefit manager, the patient's co-payment amount and the usual and customary price of the prescription or the amount the pharmacy will be paid for the prescription drug by the patient's employer-sponsored plan or health plan company, or its contracted pharmacy benefit manager.

Subd. 2. No prohibition on disclosure. No contracting agreement between an employer-sponsored health plan or health plan company, or its contracted pharmacy benefit manager, and a resident or nonresident pharmacy registered under this chapter, may prohibit the pharmacy from disclosing to patients information a pharmacy is required or given the option to provide under subdivision 1."

Changes of Address

Board staff will soon be mailing out renewal notices for technicians. Renewal notices for pharmacists will be mailed out in late December. Please make sure that the Board is notified as soon as possible of any change of address. This is required by rule and it minimizes the chance that a licensee or registrant will not receive a renewal notice. Every year, a number of individuals end up paying late fees because they have failed to notify the Board of an address change, never receive their renewal notices and, consequently, do not renew on time.

The *Minnesota Board of Pharmacy News* is published by the Minnesota Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

Cody C. Wiberg, PharmD - State News Editor

Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor

Larissa Doucette - Editorial Manager

National Association of Boards of Pharmacy Foundation, Inc
1600 Feehanville Drive
Mount Prospect, IL 60056

MINNESOTA BOARD OF PHARMACY

Presorted Standard
U.S. Postage
PAID
Chicago, Illinois
Permit No. 5744