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New Jersey Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

New Board Member

On June 20, 2005, Acting Governor Richard J. Codey appointed Thomas F.X. Bender, Jr, RPh, to the New Jersey Board of Pharmacy to replace Richard Palombo, RPh. Tom is from Hudson County and his primary area of practice is retail pharmacy. Tom currently owns several independent pharmacies in New Jersey. Rich served on the Board for 10 years including three years as president. Welcome to Tom and our sincere thanks to Rich for all of his hard work and contributions to the Board along with our best wishes.

Electronic Orders for Controlled Substances

As noted in the "National Pharmacy Compliance News" section of the July 2005 edition of this *Newsletter*, the Drug Enforcement Administration (DEA) has issued final rules regarding electronic orders for controlled substances (CS). These rules allow an electronic equivalent to DEA official order form (Form 222) which is required for all distribution of Schedule I and II CS. The state of New Jersey, Department of Law and Public Safety, Division of Law is currently researching this item to assure that the use of electronic orders is consistent with the current New Jersey statutes and regulations in order for pharmacies and wholesalers to proceed with electronic ordering of Schedule II medications in New Jersey.

APN Prescribing Controlled Dangerous Substances and Modifications to the New Jersey Prescription Blanks for APNs

The statutes that impact Advanced Practice Nurse (APN) prescribing of controlled dangerous substances (CDS) were amended in November 2004 (N.J.S.A. 45:11-49). An APN may now prescribe CDSs in all medically appropriate settings, as long as joint protocols between the APN and his or her collaborating physician permit the same. In addition, if an APN wants to prescribe CDSs, he or she must complete six contact hours of continuing education in pharmacology related to CS. The previous restriction that APNs may only prescribe CDSs under three specific sets of circumstances, is no longer in effect. The New Jersey Prescription Blank format for APNs has been modified so that it is consistent with the amended statute. The previous version, which has three boxes to check to indicate if it is a reissue, dosage change, or consistent with the statute, will be phased out and pharmacies may no longer accept prescriptions on the old version after December 31, 2005.

Clarification of 'Reduced to Writing'

The Board was asked to clarify the words "reduced to writing" in regulation N.J.A.C. 13:39-7.3(b). This regulation requires that, in order to dispense medication after all renewals listed on the original prescription have been depleted, a new prescription must be authorized by the prescriber and the new prescription must

be reduced to writing by the pharmacist and entered into either a manual or into the electronic data processing system as a new prescription. In response, the Board adopted the following policy that will be later refined and proposed as a regulation: The phrase "reduced to writing" as set forth in N.J.A.C. 13:39-7.3(b) shall include any expression by letters, numbers or characters, including handwriting, printing, typewriting, lasered, electronic, or other tangible form of recording.

Board Activities

New committees have been assigned for the many projects that are currently before the Board. The following people will be chairing the indicated committees: Tom Egan, Long Term Care and Consulting; Ira Katz, Manufacturing and Compounding; Marc Sturgill, Collaborative Practice and Immunization; Elvy Paiva, Continuous Quality Improvement; and Ed McGinley, Rules and Regulations. In addition, the Board has been working with the Board of Medical Examiners on the draft Immunization and Collaborative Practice regulations. As many of you know, it requires a considerable amount of time to draft regulations. In order for regulations to become law the draft regulations must be presented to the full Board for approval, reviewed for legal acceptability and published in the *New Jersey Register* and on the Board's Web site for public comment. The public comments are then reviewed by the committee and responses and/or changes made to the proposed regulations. If the changes are not substantive, they are then presented to the full Board for adoption and then published with an effective date.

Disciplinary Actions

The actions listed below include only those where the individual's license to practice has been revoked, surrendered, suspended, restricted, or reinstated and do not include any other actions taken by the Board. Information regarding the current status of a pharmacist's license may be obtained either at the Division of Consumer Affairs Web site or by calling the License Verification Line at 973/273-8090.

License Suspensions/Surrenders/Revocations

Timothy Morelli, RPh – On or about April 30, 2004, respondent was arrested by the Philadelphia Police Department and charged with theft of drugs, drug possession, and drug possession with the intent to distribute. Pursuant to the Consent Order, respondent's license to practice pharmacy in the state of New Jersey has been suspended. (Filed on October 7, 2004.)

John Wylie, RPh – Respondent was convicted of the crime of Theft by Deception in Superior Court, Camden County, NJ, for submitting fraudulent bills seeking insurance reimbursements and payment for performing medical procedures he was not quali-

Continued on page 4



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

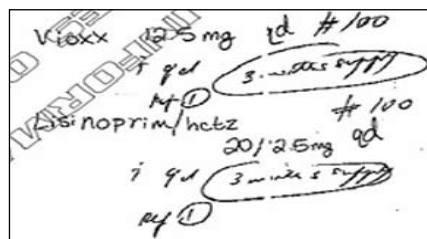
Compliance News to a particular state or jurisdiction should not be assumed. The law of such state or jurisdiction.)



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 misinterpreted 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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fied or licensed to perform. Respondent allegedly engaged in the unlicensed practice of medicine. Respondent voluntarily agreed to refrain from further practice of pharmacy and to surrender his New Jersey license. On February 4, 2005, respondent's license to practice pharmacy in New Jersey was surrendered with prejudice to reinstatement. Respondent shall pay \$5,500 dues and owing from the March 2002 Consent Order, costs for the investigation, and the investigative inquiry. (Filed on February 15, 2005.)

Anita Trego, RPh – Respondent was alleged to have diverted CDS from her employer for her own consumption. As a result, respondent voluntarily agreed to refrain from further practice of pharmacy. Pursuant to the Consent Order, respondent's license to practice pharmacy in the state of New Jersey has been suspended. Further, upon application for reinstatement, respondent shall submit documentation satisfactory to the Board inclusive of, but not limited to, weekly, random, and witnessed urine screens. (Filed on November 10, 2004.)

Linda Salvatore, RPh – Due to a serious medical condition, respondent is incapacitated and intends to no longer practice pharmacy. Respondent's license to practice pharmacy is surrendered. Should her condition sufficiently improve she may apply to the Board for reinstatement; reinstatement is conditioned upon respondent's demonstration of fitness and competence to resume the practice of pharmacy. (Filed on November 10, 2004.)

Ara Artinian, RPh – Respondent diverted CDS for his own use from his former employer's active drug stock. In lieu of a proceeding to suspend respondent's license to practice pharmacy, respondent, without admitting to any of the allegations, has agreed to surrender his license. (Filed on December 21, 2004.)

Ahmed Abouelhoda, RPh – Respondent was arrested by the Wayne Police Department on March 18, 2004, and charged with theft of drugs, drug possession with intent to distribute, and possession. The subject drugs included Steroids and CDS, Schedules II through IV. Respondent voluntarily surrendered his license until the criminal matter has been resolved. Pending further order of the Board, respondent's license to practice pharmacy in the state of New Jersey is suspended. Respondent shall cease and desist from engaging in the practice of pharmacy. (Filed on January 6, 2005.)

Eric S. Sorkin, RPh – Respondent gave false testimony to a federal grand jury and was ordered five months incarceration and, thereafter, two years supervised release. Pursuant to the Consent Order, respondent's license has been suspended. Respondent shall not apply for reinstatement prior to his completion of the criminal term of supervised release. (Filed on January 6, 2005.)

Brian Pucci, RPh – Respondent had been diverting all strengths of Oxycontin®, a Schedule II CDS, for his own use, from the active drug stock of two pharmacies. Without admitting to any of the allegations, respondent voluntarily surrendered his license pending further order of the Board. Holding an interest in the pharmacies, respondent assures that he has no access to the pharmacies, at the direction of the president of the parent corporation. Respondent's license to practice pharmacy in the state of New Jersey has been suspended. Respondent shall not enter the premises of any pharmacy owned by Rita, Inc. Upon application for reinstatement, respondent shall submit documentation satisfactory to the Board of evidencing sobriety inclusive of, but not limited to weekly random witnessed urine screens, complete treatment records of all diagnostic and rehabilitative therapy, and an in-depth, current evaluation from a Board approved psychiatrist or psychologist. (Filed on January 13, 2005.)

License Reinstatements

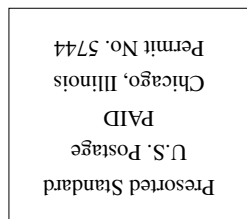
Frederick P. McLeish, RPh – Respondent has satisfied the Board that he has been sufficiently rehabilitated such that his entry into practice is consistent with public health and safety. Pursuant to the Consent Order, respondent's license to practice pharmacy in the state of New Jersey was reinstated. (Filed on October 27, 2004.)

Carol Macaulay, RPh – On March 1, 2001, respondent agreed to the voluntary surrender of her pharmacy license pending further order of the Board upon respondent's application for relicensure. Respondent shall submit documentation of her successful completion of 30 continuing education credits. Thereafter, respondent's license to practice pharmacy shall be reinstated and placed on a probationary status for three years subject to compliance with additional provisions in the Consent Order. (Filed on November 10, 2004.)

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