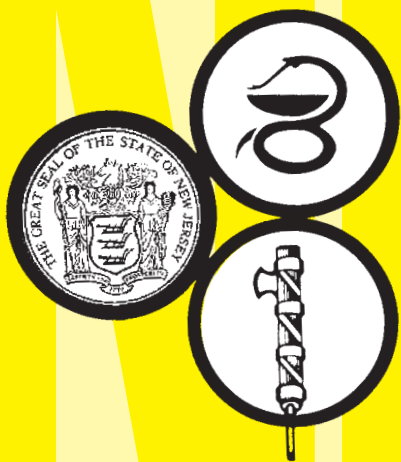


November 2004



New Jersey Board of Pharmacy

PO Box 45013
124 Halsey St, 6th Floor
Newark, NJ 07101
www.state.nj.us/lps/ca/boards.htm

Published to promote voluntary compliance of pharmacy and drug law.

Statutes and Regulations

The New Jersey Pharmacy Practice Act, which took effect on July 12, 2004, gives the New Jersey Board of Pharmacy the power and authority to register externs, interns, pharmacy preceptors, and pharmacy technicians (N.J.S.A. 45:14-48b(2)). Such registration will not take place until regulations that outline the specific processes and requirements for registration have been proposed and adopted. Similarly, many of the other changes that will take place as a result of the new Pharmacy Practice Act may **not** occur until corresponding regulations have been adopted. These include pharmacist administration of prescription medications and immunizations, pharmacist and physician collaborative drug therapy management, registration of out-of-state pharmacies, and licensure of non-dispensing practice sites.

Some of the statutory changes, however, do not require that regulations be adopted prior to their implementation. Some of these include the authorization for a pharmacist to change to a different dosage form than originally prescribed if the prescriber is notified within 48 hours following the dispensing (N.J.S.A. 45:14-60); authorization for the renewal of a prescription from a prescriber to a technician, if the prescription remains unchanged (N.J.S.A. 45:14-80b); and a pharmacist-to-technician ratio greater than 1:2 if all of the technicians have passed the National Pharmacy Technician Certification Examination.

All new regulations are published in the New Jersey Register, which is published every two weeks. All proposed and adopted regulations as well as copies of the current statutes and regulations may also be seen at the Division of Consumer Affairs Web site (www.state.nj.us/lps/ca/boards.htm). Once a regulation is proposed, anyone may submit comments regarding the proposed regulation within 60 days of the publication date. If, in response to the comments, there are no substantive changes to the proposed regulations, they are again published in the New Jersey Register for adoption. The total time from writing through adoption of new regulations can be from six months to several years, depending on the complexity of the topic.

License Reinstatement

On January 18, 2000, a new statute (N.J.S.A. 45:1-7.1d) became effective regarding the requirements that must be met in order to reinstate a professional license. This statute requires that any person who is seeking to reinstate a license that has been suspended or that has not been renewed for more than five years must successfully complete the examination required for initial licensure. The Board of Pharmacy will begin enforcing this new statute in January 2005. After this date, such persons will be required to retake and pass the North American Pharmacist Licensure Examination™ before they may receive a license to practice pharmacy in New Jersey.

Inactive License Status

A professional license may be placed on inactive status if a licensee wants to maintain his or her New Jersey Pharmacy license but does not want to engage in professional practice within the state (N.J.S.A. 45:1-7.3a). Inactive renewal of a license protects the licensee from the requirement to retake the examination. Failure to renew a license as active or inactive within 30 days of its expiration date will result in the license being suspended without a hearing (N.J.S.A. 45:1-7.1b).

DURC Formulary

Every pharmacy in the State of New Jersey is required to have a copy of the current Drug Utilization Review Council (DURC) Formulary (N.J.A.C. 13:39-7.7(a)18). Since the DURC was not funded in the July 2003 budget, it no longer exists and, therefore, it is no longer possible to obtain printed copies of the Formulary. An electronic version of the last published Formulary may be found on the following Web site: www.state.nj.us/health/mgmt/drugutil.htm.

Returned Medications

A pharmacy may accept medications returned by patients and, at the pharmacy's discretion, refund patients their money, but the pharmacy may **not** place such medications back into stock for reuse or resale (N.J.A.C. 13:39-7.10).

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 Revocations

Jennifer Kim, RPh – On October 23, 2003, respondent pled guilty to one count of third degree Health Care Claims Fraud in Superior Court of New Jersey, Bergen County. Respondent did submit bills to and receive payments from Medicaid in excess of \$35,000 knowing she was not entitled to those payments. Pursuant to the Final Order set forth, respondent's licence to practice pharmacy in the State of New Jersey was revoked. (Filed on January 7, 2004.)

Steven Aberbach, RPh – respondent pled guilty to one count of second degree Health Care Claims Fraud. Respondent has entered into a Consent Agreement with the Division of Medical Assistance and Health Services to pay restitution and fines in the amount of two hundred thousand dollars (\$200,000). Respondent has been debarred from any participation in the New Jersey Medical Assistance and Health Services Program for a period of 12 years. Pursuant to the Consent Order set forth, respondent's license to practice pharmacy

Continued on page 4



New Over-the-Counter Product Labeling

On March 24, 2004, Food and Drug Administration (FDA) passed final rulings requiring content labeling for over-the-counter (OTC) medications that contain levels of calcium, magnesium, sodium, or potassium that might be harmful to persons with certain underlying medical conditions. The final rule was effective April 23, 2004, with compliance expected by September 24, 2005. The labeling changes for oral OTC products were deemed necessary as persons with certain medical conditions such as heart disease, hypertension, kidney disease, kidney stones, or other medical conditions could worsen their condition upon consumption of these products. For example, OTC use of medications containing potassium may cause hyperkalemia in persons with compromised renal function. Under the new rules, oral OTC medications must state the exact amount of a particular ingredient in each dose if they contain:

- ◆ 5 mg or more of sodium in a single dose,
- ◆ 20 mg or more of calcium in a single dose,
- ◆ 8 mg or more of magnesium in a single dose, or
- ◆ 5 mg or more of potassium in a single dose.

The rules also require warnings to alert consumers on sodium-, calcium-, magnesium-, or potassium-restricted diets to consult their physician before using oral products that contain maximum daily doses of:

- ◆ more than 140 mg sodium,
- ◆ more than 3.2 grams calcium,
- ◆ more than 600 mg magnesium, or
- ◆ more than 975 mg potassium.

Currently the new label requirements do not include mouth rinses, fluoride toothpastes, or mouth washes. Detailed information on the rulings can be found in the Federal Register at www.fda.gov/OHRMS/DOCKETS/98fr/04-6479.htm and www.fda.gov/OHRMS/DOCKETS/98fr/04-6480.htm.

FDA Requests Antidepressant Manufacturers to Strengthen Warnings

On March 22, 2004, FDA issued a public health advisory that cautions physicians, their patients, and families and caregivers to closely monitor adults and children with depression. Results of antidepressant studies in children since June 2003 appeared to suggest an increased risk of suicidal thoughts and actions in those children taking certain antidepressants. FDA has initiated a review of these reports, but it is not clear whether or not antidepressants contribute to suicidal thinking and behavior.

As a result of the studies, FDA is asking manufacturers to change the labels of 10 drugs to include stronger cautions and warnings to monitor patients for worsening depression and the emergence of suicidal ideation. The drugs affected include bupropion (Wellbutrin®), citalopram (Celexa™), escitalopram (Lexapro™), fluvoxamine (Luvox® – not FDA approved for treatment of depression in the US), fluoxetine (Prozac®), mirtazapine (Remeron®), nefazodone (Serzone®), paroxetine (Paxil®), venlafaxine (Effexor®), and sertraline (Zoloft®). It should be noted that

Prozac is the only drug approved for use in children with major depressive disorder. Prozac, Zoloft, and Luvox are approved for pediatric patients with obsessive-compulsive disorder.

Patients taking these antidepressants should be monitored for behaviors associated with the drugs such as anxiety, agitation, panic attacks, insomnia, irritability, hostility, impulsivity, akathisia, hypomania, and mania. Physicians are urged to closely monitor patients with bipolar disorder as monotherapy with antidepressants is believed to have the potential to induce manic episodes in such patients. A causal relationship has not been established between physical symptoms and suicidal ideation; however, medications may need to be discontinued when the symptoms are severe, abrupt in onset, or were not part of the presenting symptoms. Further information can be found on CDER's Web site: www.fda.gov/cder/drug/antidepressants/default.htm.

Let Past Experience with Chloral Hydrate Syrup Guide its Safe Use



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.

Chloral hydrate can be used safely to sedate pediatric patients for diagnostic procedures such as endoscopic procedures, CT scans, or MRIs. However, in several error reports over the years we have seen the sad stories of fatalities that have occurred after excessive doses of the drug were dispensed in error. Typically, deaths have occurred in cases where the order was not clear or when untrained individuals, both staff and parents, were involved without adequate supervision or the knowledge that they were administering an overdose. In some cases, to save time, chloral hydrate has been prescribed for use at home prior to travel to the practice site. In one instance, a 500 mg/5 mL concentration was dispensed instead of 250 mg/5 mL, which also is available. Unfortunately, the dose was prescribed by volume (teaspoonful), which made detection of the twofold overdose impossible. In another incidence, 120 mL of syrup was incorrectly dispensed instead of the prescribed 12 mL. The label instructed the mother to give her child the entire bottle, which she did. Without trained personnel and emergency equipment present to treat these accidental overdoses, the children in both cases died.

Compliance News

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



Recently the tragedy happened again. A prescription was written for a 17-month-old child; the pharmacist read the directions as “30 cc before office visit” and instructed the mother to give

her child that amount. In truth, the physician wanted the child to receive 500 mg 30 minutes before the office visit. The double hash-mark symbol (“”), which the physician intended to mean minutes, was misread as cc. Actually, a double hash mark stands for seconds; a single hash mark (') is used for minutes. Neither symbol should be used in medicine, however, because not everyone understands their meaning.

Errors also happen in diagnostic areas where technical support personnel often administer oral conscious sedation even though they are not properly trained. In some cases, an ambiguous physician order such as “give chloral hydrate 5 cc prn sedation” or “. . . prn agitation,” rather than a specific milligram amount and maximum dose, has led to events where multiple doses of chloral hydrate were dispensed from the supply available to personnel. By the time the child fell asleep, the amount administered was a massive overdose leading to respiratory arrest.

Please consider reviewing your process for dispensing oral liquids used for conscious sedation in children, whether to a medical facility or to a family member. We suggest that the following precautions, in addition to package insert recommendations, be employed. Advise physicians that the drug should not be prescribed by volume (eg, “5 mL,” “one teaspoonful,” etc). There are two available concentrations of this drug. Instead, the specific milligram dose should be expressed. The prescription should state that it is for pre-procedure sedation. In hospital situations or when pharmacies dispense to health care facilities, prescriptions are best dispensed for each patient in labeled, unit-dose, oral syringes; providing the product in bulk packages as floor stock is less safe. We believe it is safest for pharmacists to *not* dispense prescriptions for patient use in the home when it is for pre-procedure sedation. Should the caregiver receive such a prescription, he or she should be advised that they are safest for the dose to be administered where the procedure will be performed. Official labeling for Versed® Syrup, another drug used for conscious sedation in children, notes that the syrup is intended for use only in monitored settings, never the home. Also, as noted in the product’s boxed warning, only health care professionals trained in conscious sedation procedures and authorized to administer conscious sedation drugs should do so. Careful monitoring by direct visual observation is necessary and age-/size- appropriate resuscitation equipment must be readily available. The American Academy of Pediatrics agrees; the Academy’s current “Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures” (*Pediatrics* 2002; 110:836-838)

recommend that children should not receive sedative or anxiolytic medications without supervision by skilled medical personnel. These medications should be administered by, or in the presence of, individuals skilled in airway management and cardiopulmonary resuscitation and administered in a health care facility where appropriate monitoring, including continuous pulse oximetry, can be instituted.

One final argument for administering children’s sedation on site is to ensure proper timing in case of unpredictable schedule delays.

NABP Releases Updated NAPLEX Blueprint

NABP has released the updated blueprint for the North American Pharmacist Licensure Examination™ (NAPLEX®). The blueprint is available for viewing on NABP’s Web site, www.nabp.net, as of September 2004. Examinations based on the updated blueprint will be administered beginning spring 2005.

Changes to the NAPLEX blueprint include the addition of competency statements addressing dietary supplements and pharmacotherapeutic equivalency as well as integration of the skill of communicating with patients and other health care providers in the entire examination blueprint instead of focusing it within a single competency area as with the current NAPLEX. The examination continues to consist of three major areas that are divided into several competency and subcompetency statements.

The updated blueprint and competency statements require a new passing standard. However, the NAPLEX continues to be a computer-adaptive examination that requires a scaled score of 75 or greater to pass. Calculation of the score is the same as in the past: the score is calculated by first determining the candidate’s ability level on the NAPLEX and then comparing this to the predetermined minimum acceptable ability level established for the NAPLEX. The new passing standard will go into effect along with the updated blueprint in spring 2005.

For more information about the NAPLEX, contact the Customer Service Department by calling 847/698-6227 or visit the Association’s Web site at www.nabp.net.

December 2004 FPGEE Date and Location Announced

On December 4, 2004, 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 Mateo, CA. Candidates who have been accepted to sit for the December 4, 2004 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.

Continued from page 1

in the State of New Jersey was revoked. Respondent shall not be a permit holder of a pharmacy in this State. Further, respondent shall not manage a pharmacy or participate in the billing and collecting activity for any pharmacy in this State. (Filed on January 7, 2004.)

Kwadwo Agyemang, RPh – respondent was convicted of one count of third degree Health Care Claims Fraud in Superior Court of New Jersey, Essex County. Specifically, respondent did submit bills to and receive payments from Medicaid in excess of twenty-seven thousand dollars (\$27,000). Pursuant to the Final Order set forth, respondent's license to practice pharmacy in the State of New Jersey was revoked. (Filed on January 14, 2004.)

Matthew Faenza, RPh – On October 17, 2003, respondent was convicted of second degree Health Care Claims Fraud in Superior Court of New Jersey, Passaic County. Specifically, respondent did submit bills to and receive payments from Medicaid in excess of \$450,000 knowing he was not entitled to those payments. Respondent's license to practice pharmacy in the State of New Jersey was revoked. (Filed on February 18, 2004.)

Michael Stavitski, RPh – Respondent pled guilty to second degree crimes of Health Care Claims Fraud in New Jersey Superior Court, Monmouth County. Specifically, respondent knowingly submitted fraudulent health care claims to Medicaid in excess of one million dollars. Respondent's right to reinstate his license to practice pharmacy in the State of New Jersey was revoked with prejudice to reinstatement. (Filed on February 18, 2004.)

Jainarain Singh, RPh – Entered into his employer's computer fraudulent prescriptions for himself and his wife and his daughter, and had them filled and delivered to his home address while working at Medco Health Solutions, Inc, of Parsippany from November of 1995 through June of 2003. The majority of the fraudulent prescriptions dispensed to the respondent were for large quantities of high-priced medications. Respondent's license to practice pharmacy in the State of New Jersey was a voluntary surrender with prejudice to reinstatement to be deemed a revocation. (Filed on March 15, 2004.)

License Suspensions/Surrenders

Barbara Ann Pesciotta, RPh – Arrested on November 13, 2003, in Dover Township and charged with Driving Under the Influence, possession of oxycodone, marijuana and drug paraphernalia. Respondent's license to practice pharmacy was surrendered. (Filed on February 11, 2004.)

Howard Wertheim, RPh – On November 24, 2003, respondent was arrested and charged with knowingly possessing lorazepam, a Schedule IV controlled dangerous substance; possession of lorazepam with intent to distribute, and knowingly distributing lorazepam. At the time of his arrest respondent had small amounts of controlled dangerous drugs in his possession for his own use

diverted from Panther Valley's active drug stock. Respondent's license to practice pharmacy in the State of New Jersey has been suspended. Respondent is not to apply for reinstatement prior to January 14, 2005. (Filed on February 25, 2004.)

Guiseppe Cucaro, RPh – Diverted controlled dangerous substances, Vicodin® and hydrocodone, controlled dangerous substances, from his former employer's active drug stock. Respondent's license to practice pharmacy was surrendered. (Filed on May 12, 2004.)

Jong Pak, RPh – Diverted hydrocodone and Vicodin, both controlled dangerous substances, from the active drug stock of his employer. Respondent's license to practice pharmacy was surrendered. (Filed on May 12, 2004.)

License Reinstatements

Kenneth Enemu, RPh – As of January 7, 2004, respondent has entered into an Order with the Board to reinstate his license to practice pharmacy pending proof of his successful completion of 75 continuing education credits, and the Law Exam, and the successful completion of a 500-hour practicum under the immediate supervision of a Board-approved preceptor. Respondent shall not act as the pharmacist-in-charge at any pharmacy nor have ownership interest in any pharmacy. Respondent is barred from dealing with Medicare/Medicaid patients or patients in any federally and/or state funded programs. Respondent shall present a copy of this Order to any future employer, including his preceptor, prior to commencement of work. The preceptor and employer are to inform the Board in writing that they have received and understand the terms set forth in the Order. (Filed on January 7, 2004.)

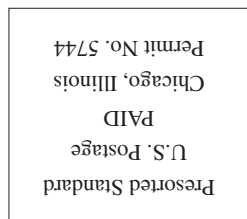
Joseph De Marinis, Jr, RPh – Modified Order of Reinstatement – After a thorough review by the Board, the respondent's license shall only be subject to being prohibited as acting as the pharmacist-in-charge at any pharmacy and he shall not own or have an ownership interest in any pharmacy. In addition, respondent shall present a copy of this Order to any future employer prior to commencing work as a licensee and shall ensure that his employer notifies the Board in writing he or she has received and understands the terms of the Order. (Filed on January 22, 2004.)

Page 4 – November 2004

The *New Jersey Board of Pharmacy News* is published by the New Jersey 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.

New Jersey Board of Pharmacy - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor
& Executive Editor

Reneeta C. "Rene" Renganathan - Editorial Manager



NEW JERSEY BOARD OF PHARMACY
National Association of Boards of Pharmacy Foundation, Inc
700 Busse Highway
Park Ridge, Illinois 60066