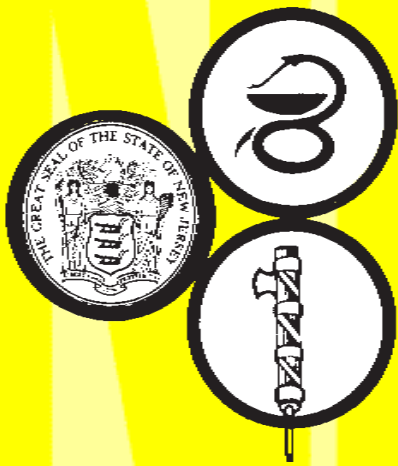


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# New Jersey Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

## **Waiver of CE Requirements for Initial License Renewal**

According to NJAC 13:39-3A1(a) "Each applicant for biennial license renewal shall complete a minimum of 30 credits of continuing education during the preceding biennial period, except that the Board shall not require completion of continuing education credits for an applicant's initial license renewal." Confusion has arisen regarding the length of this initial continuing education waiver. New licensees should note that NJAC 13:39-3A1(a) does not infer that every new licensee is granted a two-year waiver of continuing education requirements. Rather, continuing education is not required for the remainder of the biennial renewal period during which the individual is licensed. For example, the current biennial renewal period runs through April 30, 2009. An individual who was initially licensed in New Jersey in May 2007 would have a two-year waiver period, whereas a new pharmacist licensed in January 2009 would have only a four-month waiver. To summarize, neither individual in the example would need to report continuing education in 2009, but both would need to complete and report the required continuing education for 2011.

## **Introductory Professional Practice Experience**

The Accreditation Council for Pharmacy Education (ACPE) published updated *Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree* in 2007. The new guidelines mandate 300 hours of Introductory Pharmacy Practice Experience (IPPE) training for all students. ACPE recommends that these hours be spread out over a three-year period, beginning with the first professional year (year three of the six-year curriculum). The purpose of IPPE training is to provide students with real practice experience, including direct interaction with patients in community pharmacy, institutional pharmacy, or other pharmacy practice settings. Students must be supervised by a pharmacist preceptor, and they are not allowed to be paid. Along with the 300 hour IPPE requirement, the 2007 ACPE guidelines also require 1,440 hours (or 36 weeks) of Advanced Pharmacy Practice Experience (APPE) training. The APPE requirement is met during the fourth professional year (or the final year of the six-year curriculum).

## **Storage and Dispensing of High-Alert Medications**

The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) defines a medication error as "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use."

A medication error involving a high-alert medication can have tragic consequences. The erroneous dispensing of methotrexate 2.5 mg for minoxidil 2.5 mg, and Purinethol® 50 mg for propylthiouracil 50 mg are just two examples of medication errors associated with patient fatalities that have occurred in New Jersey. The Institute for Safe Medication Practices (ISMP) publishes a list of high-alert medications, which are defined as "drugs that bear a heightened risk of causing significant patient harm when they are used in error." Examples include intravenous (IV) adrenergic agonists such as epinephrine, IV adrenergic antagonists such as propranolol, antithrombotic agents such as warfarin, chemotherapeutic agents, oral hypoglycemic agents, and total parenteral nutrition solutions. ISMP recommends additional safeguards to minimize the risk of selecting the wrong medication when filling and dispensing a prescription for a high-alert medication. These safeguards may include improving pharmacist access to drug information, storing high-alert medications in such a way as to limit access to them, using auxiliary labels and automated alerts, and employing a standardized process for ordering, storage, and dispensing. In addition, ISMP recommends the use of manual redundancies such as independent double-checks when these medications are dispensed. Licensees are encouraged to review the ISMP list of high-alert medications and recommendations for preventing medication errors. The ISMP Web site is located at [www.ismp.org](http://www.ismp.org).

## **Recognizing Fraudulent Prescriptions**

Fraudulent prescriptions for controlled dangerous substances continue to present a significant problem to dispensing pharma-

*Continued on page 4*



## Study Fuels Concerns over Foreign Drugs Bought Online

According to study results published in the May 2008 issue of *Annals of Pharmacotherapy*, many prescription medications purchased from foreign pharmacies through Internet drug outlets differ significantly from the versions approved by the Food and Drug Administration (FDA). "These findings have implications for safety and effectiveness that should be considered by clinicians to potentially safeguard patients who choose to purchase foreign-manufactured drugs via the Internet," the study authors say.

The study evaluated 20 simvastatin tablets and capsules, including the US innovator product and 19 generic samples obtained from international Internet drug outlets. Tablet samples were tested according to United States Pharmacopeia (USP) guidelines where applicable, using high-performance liquid chromatography, disintegration, dissolution, weight variation, hardness, and assessment of physical characteristics.

Several international samples analyzed were not comparable to the US product in one or more aspects of quality assurance testing, and significant variability was found among foreign-made tablets themselves. Five samples failed to meet USP standards for dissolution, and two for content uniformity. Among all samples, variability was observed in hardness, weight, and physical characterization.

## Testing Medication Names Prior to Marketing



*This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with 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, and publishes its recommendations. To read about the recommendations for prevention of reported errors that you can put into practice today, subscribe to **ISMP Medication Safety Alert!**<sup>®</sup> **Community/Ambulatory Edition** by visiting [www.ismp.org](http://www.ismp.org). 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 Medi-*

*cation Errors Reporting Program. ISMP address: 200 Lakeside Dr, Horsham, PA 19044. Phone: 215/947-7797. E-mail: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org).*

Medication names that look-alike and sound-alike, confusing or absent drug labeling, and non-distinct or ambiguous drug packaging significantly contributes to medication errors. This is not a new problem. These conditions have led to serious drug mix-ups and deaths. Research has identified that one of the most frequent causes of pharmacy drug dispensing errors (29%) is failure to accurately identify drugs, most prominently due to look-and sound-alike drug names (Leape et al. JAMA, July 5, 1995).

In addition, many medications are packaged in bottles with similar shapes and similar labels, making it easy to confuse one drug with another.

MedMARX data reports there are 1,470 different drugs implicated in medication errors due to brand and/or generic names that looked or sounded alike. From this data, USP has compiled a list of 3,170 pairs of names that look and/or sound alike.

FDA is also concerned about drug naming confusion and its subsequent potential error effects. On June 5-6, 2008, FDA hosted a public workshop to discuss a concept paper ([www.fda.gov/cder/drug/MedErrors/meeting\\_names.pdf](http://www.fda.gov/cder/drug/MedErrors/meeting_names.pdf)) about a pilot program to address look- and sound-alike brand names. The pilot, called for in the FDA Amendments Act of 2007, would allow drug companies (or outside contractors) to voluntarily evaluate proposed brand names and submit the data for review to FDA. Currently, FDA's Division of Medication Error Prevention screens drug names using its own safety testing methods, in consultation with other divisions responsible for product approval.

The concept paper outlines the types of studies that should be conducted, including simulations of real-world conditions with practicing clinicians who evaluate handwritten, electronic, and oral prescribing scenarios to detect name similarities and other potential confusion with laboratory and medical terms or abbreviations. Dosage form, strength, and frequency also should be considered, as well as the clinical environment where it will be used. Based on discussions during the June meeting and submitted comments, FDA will revise the concept paper and present testing methods to the pharmaceutical industry.

It is hoped that testing drug names prior to marketing will decrease the number of look-and sound-alike medication names. ISMP receives numerous reports of



errors and potential errors caused by look-and-sound-alike medications every year. ISMP, through its wholly owned for-profit subsidiary Med-E.R.R.S., Inc<sup>®</sup>, has been reviewing drug names and packaging for pharmaceutical manufacturers for more than 10 years.

If you are a pharmacist or other health care practitioner who is interested in medication safety and error prevention, you can make a difference! Med-E.R.R.S. is looking for pharmacists from all practice settings to help test labeling, packaging, and nomenclature in the pre-marketing phase for pharmaceutical companies. The process is fun, simple, and easy and a small honorarium is paid for your participation.

For more information or to sign up, go to [www.med-errs.com](http://www.med-errs.com) and click on "Become a Reviewer."

## **Coalition Looks to Pharmacies, Regulators to Reduce Diversion**

A recent report by the Coalition Against Insurance Fraud looks to pharmacies and pharmacy regulators, among others, to cut down on the prevalence of prescription drug diversion, particularly of controlled substance analgesics.

The report, "Prescription for Peril: How Insurance Fraud Finances Theft and Abuse of Addictive Prescription Drugs," calls on the pharmacy profession to provide additional training on prescription drug abuse and diversion in pharmacy education curricula and continuing professional education, and to exert closer point-of-sale scrutiny of certain prescriptions and patients. For instance, the report suggests diversion could be reduced significantly if pharmacies asked for photo identification in connection with controlled substance prescriptions, similar to regulations in place for pseudoephedrine-containing products.

The coalition also recommends wider adoption of prescription monitoring programs to maintain state-wide records of narcotic prescriptions, allowing closer monitoring by prescribers and dispensers. In addition, the coalition calls on lawmakers and licensing boards to "swiftly and decisively penalize the small fraction of prescribers and dispensers who facilitate drug diversion and abuse."

## **FDA Encourages Pharmacists to Use Patient Safety News**

*FDA Patient Safety News* is a monthly video news program produced by FDA targeted to pharmacists and other health care professionals. The program provides the

latest information on recalled and counterfeit products, important safety alerts, preventing medical errors and mitigating risks from the use of medical products, including drugs, devices, vaccines, and diagnostic products.

The videos can be watched online or downloaded free of charge. Pharmacists can view the entire program or individual segments, and FDA encourages further use and distribution of the video or text of the program, as there are no copyright restrictions. The video and demonstrations can also be used in staff-development programs or in other teaching environments.

Pharmacists can search for video segments on topics of interest, get additional information about topics, e-mail segments to others, report problems with medical products to FDA, and sign up to be notified about each month's program. The show is also broadcast on several medical satellite networks: VHA, GE TiP-TV, HSTN, LTCN, and HNN. These networks presently reach over 4,000 hospitals and long-term care facilities across the US.

More information about the program and how to join the program mailing list is available on the FDA Web site at [www.fda.gov/psn](http://www.fda.gov/psn) or by sending an e-mail to [PSNews@cdrh.fda.gov](mailto:PSNews@cdrh.fda.gov).

## **Switch to HFA-Propelled Albuterol Inhalers Advised in Anticipation of CFC Ban**

FDA recently issued a public health advisory alerting patients, caregivers, and health care professionals to switch to hydrofluoroalkane (HFA)-propelled albuterol inhalers because chlorofluorocarbon (CFC)-propelled inhalers will not be available in the United States after 2008. CFC-propelled albuterol inhalers are being phased out to comply with the Clean Air Act and an international environmental treaty, the Montreal Protocol on Substances that Deplete the Ozone Layer. Under this treaty, the US has agreed to phase out production and importation of ozone-depleting substances including CFCs. No CFC-propelled albuterol inhalers may be produced, marketed, or sold in the US after December 31. Three HFA-propelled albuterol inhalers have been approved by FDA: Proair<sup>®</sup> HFA Inhalation Aerosol, Proventil<sup>®</sup> HFA Inhalation Aerosol, and Ventolin<sup>®</sup> HFA Inhalation Aerosol. In addition, an HFA-propelled inhaler containing levalbuterol is available as Xopenex<sup>®</sup> HFA Inhalation Aerosol. More information is available on the FDA Web site at [www.fda.gov/cder/mdi/albuterol.htm](http://www.fda.gov/cder/mdi/albuterol.htm).

cists. A Web page entitled “A Pharmacist’s Guide to Prescription Fraud,” published by the Drug Enforcement Administration (DEA) Office of Diversion Control, discusses patient or prescriber behaviors and prescription characteristics that may indicate prescription fraud. Behaviors that should alert the pharmacist to the possibility of fraud include:

1. a prescriber who writes controlled dangerous substance prescriptions much more frequently or for much larger quantity than other prescribers in your area;
2. a prescriber who writes simultaneously for antagonistic medications (both central nervous system stimulants and depressants, for example);
3. a patient who returns to refill a medication too frequently;
4. a patient presenting prescriptions written for other individuals;
5. multiple patients appearing simultaneously or within a short time period, all with prescriptions from the same prescriber, and;
6. multiple new patients suddenly appearing, all with prescriptions from the same prescriber.

Characteristics that may indicate the possibility of a fraudulent prescription include:

1. handwriting that is too legible;
2. the use of nonstandard abbreviations;
3. directions for use that contain no abbreviations;
4. drug dosage, directions for use, or quantity dispensed that differs from the typical use of the medication;
5. a prescription that appears to be photocopied; or
6. a prescription written in different ink colors or containing sections in different handwriting.

Dispensing pharmacists assume the responsibility for taking reasonable steps to prevent prescription fraud. These steps may include:

1. becoming familiar with the handwriting, and knowing the DEA registration number, of prescribers who commonly write prescriptions in your area;
2. getting to know the patients who commonly fill prescriptions in your pharmacy;
3. becoming familiar with the medications that are commonly associated with prescription fraud in your area;

4. checking the date on the prescription to see that it has been presented in a reasonable amount of time from the date it was written;
5. calling the prescriber for verification whenever there is a concern; or
6. requesting proper identification from the patient when there is a concern.

Effective communication with prescribers and other pharmacists in the area can be an effective deterrent. If presented with a prescription that you suspect is fraudulent do not dispense the medication and contact your local law enforcement. If you suspect a pattern of prescription fraud, contact the Board of Pharmacy or your local DEA office. The DEA Office of Diversion Control Web site is located at [www.dea diversion.usdoj.gov](http://www.dea diversion.usdoj.gov).

### **Pharmacy Technician Registration**

Please note that December 1, 2008, is the deadline for registration with the Board of Pharmacy for all pharmacy technicians hired prior to September 4, 2007. Unregistered pharmacy technicians hired prior to September 4, 2007, must cease performing any pharmacy technician functions on December 1, 2008. Pharmacy technicians hired after September 4, 2007, may be designated as pharmacy technician applicants for a period of time not to exceed 180 days, beginning on December 1, 2008. Pharmacy technician applicants must submit an application with the Board of Pharmacy to begin the registration process consistent with NJAC 13:39-6.6.