

October 2008



# North Carolina Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

## **Item 2172 – Online License Renewals and Online Reporting of Continuing Education**

Pharmacists are reminded that, effective January 1, 2008, new continuing education (CE) requirements are in effect. To renew a pharmacist license for 2009, the licensee must acquire fifteen (15) hours of CE, and eight (8) of those hours must be contact hours. Up to five (5) surplus CE hours may be carried over for up to one (1) year. In other words, a pharmacist who acquires twenty (20) hours of CE in 2008 may carry over the excess five (5) into 2009.

A new feature has been added to the North Carolina Board of Pharmacy Web site that will allow pharmacists to enter their CE as it is accumulated any time throughout the year. To access, go to the pharmacist login page at <https://www.ncbop1.org/online/pharmacist-login.asp> (a link to this can also be found on our Web site's main menu under "Pharmacists"). Type in your license number and PIN (last four digits of your Social Security number). Under the "Pharmacist" main menu select "Continuing Education" and you will be allowed to add your CE hours. By selecting the year in the drop-down menu you may view your CE for each calendar year. Please note that in order to renew your pharmacist license, your CE information must be entered through this system and kept current. **Otherwise, the online renewal system will not permit a license renewal at the end of the year.** As you know the Board continues to conduct random CE audits and pharmacists are required to keep CE certificates for three (3) years.

Feedback on the online CE reporting system to date has been overwhelmingly positive. Pharmacists with suggestions for improvement should provide them to Board staff. Once the renewal season is complete, Board staff will revisit the system and make any necessary improvements.

Accordingly, pharmacists are reminded that **renewals of all licenses and registrations for 2009 will only be allowed online.** No paper renewals will be accepted, nor will any paper renewals be sent to licensees or registrants. If you wish to receive electronic reminders about renewal for 2009, please make sure that the Board has a valid e-mail address for you.

## **Item 2173 – Importance of Confirming Pharmacists' Identity and Credentials**

Making sure that the person you are contemplating employing as a pharmacist is, in fact, who they claim to be and is licensed as a pharmacist should strike most as obvious. A handful of recent incidents in North Carolina serve as a stark reminder, however, of the importance of this seemingly simple task.

In 2006, Board staff received information that a pharmacy technician was representing herself as a graduate of a foreign pharmacy school

who had completed all Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) requirements and was simply awaiting licensure in North Carolina. Board staff believes that this person told the story to get hired as a pharmacy intern at significantly higher pay than is typically available to a pharmacy technician. Board staff confirmed through the National Association of Boards of Pharmacy® that this person's foreign pharmacy school credentials were forged and that she had never completed any of the FPGEC requirements for licensure, much less all of them.

Earlier this year, a person represented to a hospital pharmacy that she was a recent graduate of the University of North Carolina School of Pharmacy (UNC) and was awaiting issuance of her license by North Carolina. Alert personnel at the hospital questioned this representation and Board staff confirmed that this person had never been a student at UNC, or any other school of pharmacy.

Most recently, a person appears to have stolen the identity of a North Carolina licensed pharmacist – including college transcripts and license renewal papers – and passed himself off as that pharmacist in an attempt to obtain employment at no fewer than two hospital pharmacies in western North Carolina. Once again, alert hospital personnel raised suspicions, allowing Board staff to confirm not only that the person was not who he represented himself to be, but also that he had served time in prison for prescription forgery. This person has since been arrested by law enforcement and charged with a number of crimes.

In this most recent case, the identity thief came to the attention of potential employers via a recruiting (or "headhunting") service. Board staff spoke with the recruiting service (and, in a handful of prior disciplinary matters, have had similar discussions with other services). To put it bluntly, Board staff was shocked with how lax the recruiting services it spoke with are when it comes to conducting even the most minimal verification of their clients' purported credentials. Indeed, it is probably far more accurate to call these verification procedures nonexistent. Accordingly, employers should not, and must not, accept at face value representations made by a candidate for employment or his or her recruiting service about the candidate's credentials.

Each pharmacist manager is reminded that he or she is the "person who **accepts responsibility** for the operation of a pharmacy in conformance with all statutes and regulations pertinent to the practice of pharmacy and distribution of drugs by signing the permit application, its renewal or addenda thereto." 21 NCAC 46.1317(25). Among those responsibilities is ensuring that properly trained and credentialed staff work in the pharmacy. Vigilance in the recruiting and hiring process is a must.



## 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).



## **Item 2174 – Reciprocity of Florida Licenses to Practice Pharmacy**

For many years, the state of Florida did not accept licenses by reciprocity. Several years ago, Florida altered their process somewhat to allow reciprocity of licenses where the reciprocity candidate had taken and passed the North American Pharmacist Licensure Examination™ (NAPLEX®) within 12 years of the date of reciprocity application. Given these limitations, the North Carolina Board refused to allow Florida licensees to reciprocate their licenses to North Carolina.

In June 2008, the Florida legislature passed, and the governor of Florida signed into law, legislation removing the “twelve-year” limitation on reciprocity of pharmacy licenses to Florida. In response, the North Carolina Board agreed at the July 15, 2008 meeting to allow Florida pharmacists to reciprocate their licenses to North Carolina in accordance with all the procedures and substantive requirements applicable to reciprocity candidates from any other state.

North Carolina pharmacists who wish to reciprocate their licenses to Florida should contact the Florida Board of Pharmacy for instructions.

## **Item 2175 – Acquisition of Internship Hours By Graduates of Foreign Schools of Pharmacy**

Effective August 1, 2008, any graduate of a foreign school of pharmacy who wishes to begin acquiring the 1,500 experiential hours required for licensure as a pharmacist in North Carolina must first provide to the Board of Pharmacy proof that he or she has obtained FPGEC certification. This policy brings North Carolina into line with virtually all other states on this issue.

## **Item 2176 – Upcoming Board Elections**

Board staff members have received a number of inquiries concerning upcoming Board elections. The next Board election will take place in **April/May 2009**. Two positions on the Board will be filled: the Northeastern District seat presently held by Wallace Nelson, and the Central District seat presently held by Stan Haywood. Messrs. Nelson and Haywood will complete their second consecutive five-year terms on April 30, 2010, and thus are term limited. Following the 2009 election, the Board members-elect will serve a one-year learning term before assuming their seats May 1, 2010.

The Northeastern District comprises Bertie, Camden, Chowan, Currituck, Dare, Durham, Edgecombe, Franklin, Gates, Granville, Halifax, Hertford, Hyde, Martin, Nash, Northampton, Pasquotank, Perquimans, Tyrell, Vance, Wake, Warren, Washington, and Wilson counties.

The Central District comprises Anson, Cabarrus, Chatham, Davidson, Davie, Iredell, Lee, Mecklenburg, Montgomery, Moore, Randolph, Richmond, Rowan Stanly, and Union counties.

A Board member elected from a district must be a resident of that district at the time of election. All pharmacists licensed and residing in North Carolina are eligible to vote in the election. Candidates for the Board may be nominated by the Board’s Committee on Nominations or may be made by petition of ten (10) eligible voters from the relevant district. Petitions must be filed in the Board office or postmarked by March 10, 2009, and all nominations are closed by March 15, 2009.

Subsequent elections are as follows:

**April/May 2010.** Election for the Southeastern District seat presently held by Joey McLaughlin. Mr McLaughlin is serving his first five-year term and thus is eligible to run for re-election.

The Southeastern District comprises Beaufort, Bladen, Brunswick, Carteret, Columbus, Craven, Cumberland, Duplin, Greene, Harnett, Hoke, Johnston, Jones, Lenoir, New Hanover, Onslow, Pamlico, Pender, Pitt, Robeson, Sampson, Scotland, and Wayne counties.

The winner of this election will begin his or her term May 1, 2011.

**April/May 2011.** Election for the Northern District seat presently held by Betty Dennis, and the Western District seat presently held by Rebecca Chater. Dr Dennis and Mrs Chater will complete their second consecutive five-year terms on April 30, 2012 and thus are term limited.

The Northern District comprises Alamance, Caswell, Forsyth, Guilford, Orange, Person, Rockingham, Stokes, Surry, and Yadkin counties.

The Western District comprises Alexander, Allegheny, Ashe, Avery, Buncombe, Burke, Caldwell, Catawba, Cherokee, Clay, Cleveland, Gaston, Graham, Haywood, Henderson, Jackson, Lincoln, Macon, Madison, McDowell, Mitchell, Polk, Rutherford, Swain, Transylvania, Watauga, Wilkes, and Yancey counties.

Winners of this election will begin their terms May 1, 2012.

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