February 2009

# SC Department of Labor, Licensing & Regulation – Board of Pharmacy

Kingstree Bldg, 110 Centerview Dr
PO Box 11927, Columbia, SC 29211-1927
*www.llr.state.sc.us/pol/pharmacy,* 803/896-4700

**Published to promote voluntary compliance of pharmacy and drug law.**

## *2009 Pharmacist Renewal Notices Are Coming Soon!*

The 2009 renewal notices will be mailed to you on or about March 1. The South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy has enhanced its online renewal system to make it easier and more convenient for you to renew your license. You will receive a renewal notice that includes a **userID** and a **password** that will allow you to access the online renewal Web site. If you choose not to renew online, you can request a paper renewal form from the Office of Licensure and Compliance and renew by mailing the completed form and proper fees to the Office of Licensure and Compliance. Applications for renewal must be filed before March 31, 2009, in order to avoid penalty. If you are not using online renewal, please document carefully the date that the application is mailed. Postage machines do not provide acceptable proof of mailing.

Applications submitted for renewal between April 1 and April 30, 2009, must include a penalty of $50 for late renewal in addition to evidence that the applicant meets the renewal requirements and has paid the appropriate fees. If you do not renew your license by April 30, 2009, it will be considered lapsed. You can be disciplined for unlicensed practice if you continue to work in South Carolina after that date.

### Continuing Education for Pharmacist Renewals

In order to renew online you must indicate that you have completed the required 15 hours of continuing education (CE) (6 hours must be live). You cannot renew until you have completed the CE requirements. After renewals are processed, a random CE audit will be conducted. If you are selected for the audit, please respond promptly. Disciplinary action will be taken if you cannot show that you completed the CE requirements or if the required CE are dated **after** your renewal is received in our office.

## *Compliance Tips*

### Bulk Products used for Compounding Medications

The following information is taken from United States Pharmacopeia Chapter 797, "Pharmaceutical Compounding – Sterile Preparations" in the section on "Ingredients and Devices – Nonsterile Ingredients and Devices":

> Bulk and unformulated drug substances and added substances or excipients shall be stored in tightly closed containers under temperature, humidity and lighting conditions that are either indicated in official monographs or approved by suppliers. The date of receipt by the compounding facility shall be clearly and indelibly marked on each package of ingredient. After receipt by the compounding facility, packages of ingredients that lack a supplier's expiration date cannot be used after 1 year unless either appropriate inspection or testing indicates that the ingredient has retained its purity and quality for the use in the CSPs.

For bulk or unformulated drug substances used in **non-sterile or sterile compounding**, the compounding facility shall keep the certificate of analysis for its bulk drugs. The inspectors will recommend for all bulk drug substances that the container is dated the day it is opened and discarded one year later. As a reminder, it is the facility's responsibility to prove the ingredient has retained its quality/potency.

### Disposal of Powders or Other Medications

In an effort to protect the environment and reduce the chance of medications getting into the wrong hands it is recommended that any facility that has outdated powders or other medications that need to be destroyed should look into a company that will pick-up these products to be incinerated.

RxWiki posted the following article on its Web site about the disposal of medications which you can print and share with your patients.

> **Proper Disposal of Prescription Drugs**
> The White House Office of National Drug Control Policy, the Department of Health and Human Services, and the Environmental Protection Agency jointly released new guidelines back in February 2008, which are designed to reduce the diversion of prescription drugs, while also protecting the environment.
> The new federal prescription drug disposal guidelines urge Americans to:

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## FDA Web Site Upgrades Support MedWatch's Patient Safety Goal

Two recently launched additions to the Food and Drug Administration's (FDA) Web site are intended to support the "Patient Safety" goal that MedWatch shares in public health efforts to protect patients from serious harm and improve outcomes. The entry pages assist health care professionals and patients to locate timely safety information for FDA-regulated human medical products and assist them in making diagnostic and therapeutic decisions.

The content and links on the new FDA entry page specifically for health care professionals allows busy doctors, pharmacists, nurses, and other health care professionals to find information to make point-of-care decisions. There is information that is specifically safety-related, such as easy access to reporting adverse events or finding new safety alerts, warnings, and recalls. Users can also find content regarding new approvals information, or access to the current version of the label, or prescribing information in "DailyMed." This page can be accessed through *www.fda.gov/healthprofessionals*.

FDA's other new page is specifically for patients and provides two patient-friendly articles about reporting adverse events and product quality problems to FDA and to the patient's caregivers. These articles are also available to pharmacists in printer-friendly PDF versions that can be downloaded and distributed to patients. FDA relies on properly and timely reporting of serious and unexpected drug and device-related adverse events, use errors, and quality problems. Pharmacists can ascertain and teach their patients to understand the "what, why, and how" to report to FDA and also learn about what happens to each received report and whether it leads to FDA action that may make product use safer for both patients and providers. FDA's patient specific page can be found at *www.fda.gov/consumer/default.htm*.

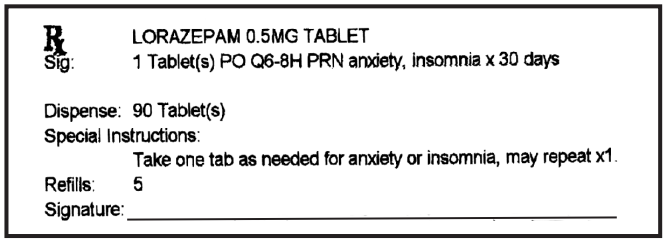
## Retail Pharmacies Now Providing Medical Clinics to Improve Public Safety

*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!® Community/Ambulatory Edition*** *by visiting www.ismp.org. 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: 200 Lakeside Dr, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

Retail pharmacy corporations have set up medical clinics within pharmacies. These nurse-practitioner or physician-assistant run clinics aim to rapidly diagnose and treat a limited number of health problems. Many also offer vaccination programs. The first pharmacy-based medical clinics were opened in Minnesota as QuickMedx in 2000, later becoming MinuteClinic in 2002. Currently there are approximately 1,000 sites in 37 states representing almost three million cumulative visits.

The emergence of pharmacy-based medical clinics offers a unique set of opportunities to improve the safety in prescribing and dispensing medications. Do you have a clinic opening in your store? If so, consider these safety recommendations:

- Meet the nurse practitioners and physician assistants and introduce them to your staff. Show them how your operation works and invite them in for a tour.
- If you have prescription scanning capabilities, show them how a scanned prescription displays on your monitor. Show them how different prescription blanks scan (eg, colored prescription blanks, blanks with water marks or seals for diversion) and what to avoid using so as not to distort the actual order.
- If they are using a device that allows them to send prescriptions electronically, have them send test prescriptions to you, invite them in to see how their prescriptions display on your computer and send them back test refill requests.
- Work together on any issues that arise, such as conflicting directions and special instructions, where the automatic sig indicates one set of patient directions and then the free text special instructions contradict the sig (see image below).


Rx
Sig: LORAZEPAM 0.5MG TABLET
1 Tablet(s) PO Q6-8H PRN anxiety, insomnia x 30 days

Dispense: 90 Tablet(s)
Special Instructions:
Take one tab as needed for anxiety or insomnia, may repeat x1.
Refills: 5
Signature: _____

- Ask prescribers to include the indication for use whenever they write or call in a prescription.
- Educate them that it is your policy to read back the entire prescription order to them after transcribing it in the pharmacy including spelling the medication name. Let them know you will be using "cock-pit" language, for example, "one six" for "16."
- Ask them to include both the generic and brand names on all written orders for medications with look-alike and/or sound-alike names.
- Share with them ISMP safety tools (eg, List of Error Prone Abbreviations, List of Confused Drug Names) found at *www.ismp.org/Tools*.

- Let them know you will dispense measuring devices every time they order a liquid medication.
- Let them know that safety is your priority when filling prescriptions, and invite them to be part of your safety team.

## FDA Launches Web Sites on Promotion of Medical Products

On September 3, 2008, FDA launched two new Web sites to provide information for consumers and industry about how FDA regulates the promotion of medical products. Pharmacists can obtain useful information regarding prescription drug advertising regulations as well as refer their patients who may have questions to the site.

The "Advertising Prescription Drugs and Medical Devices" Web site provides a "one-stop shop" portal to information on FDA regulation of medical product promotion. Pharmacists access relevant laws, regulations, and guidances. This site can be found at *www.fda.gov/oc/promotion/*.

The direct-to-consumer Web site, "Be Smart about Prescription Drug Advertising: A Guide for Consumers" is designed to educate consumers about how to view such advertising to help inform their discussions with health care providers, and consequently to help improve patient's understanding and medical care. This site was created in collaboration with EthicAd, an independent, nonprofit organization dedicated to helping consumers, health care professionals, and the pharmaceutical and advertising industries with direct-to-consumer advertising for prescription drugs. More information can be found at *www.ethicad.org*.

The direct-to-consumer site provides interactive example ads for fictitious drugs to illustrate the different requirements for the various types of ads. It also includes a list of questions patients should ask themselves when they see a prescription drug ad. This list can be printed for patients to use while discussing questions with their health care providers. This site can be found at *www.fda.gov/cder/ethicad/index.htm*.

## FPGEE Returns to Computer-based Format

As advancements in secure testing technology forge ahead, the push for more electronically based systems and less use of the traditional paper-and-pencil mechanisms continues. With this in mind, NABP will soon be returning the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) to a computer-based format, eliminating the paper-and-pencil examination.

The FPGEE is the third computerized examination to be developed by NABP, after the North American Pharmacist Licensure Examination® (NAPLEX®) and Multistate Pharmacy Jurisprudence Examination® (MPJE®). The new computerized FPGEE will debut at the April 14, 2009 administration.

The computerized FPGEE examination will continue to be administered one day in the spring and one day in the fall; however, instead of limiting the available testing locations to three sites, applicants will be able to choose from more than 200 Pearson VUE testing sites located within the continental United States. In addition, it is anticipitated that applicants will be able to schedule their test sites electronically 48 to 72 hours after having been accepted to take the FPGEE.

The NABP test vendor, Pearson VUE, will administer the computerized FPGEE as it does with the NAPLEX and the MPJE. Demonstrating a record of solid customer service combined with a secure and consistent test center network, Pearson VUE is committed to providing a reliable and professional testing environment for applicants on behalf of NABP.

The FPGEE is one component of the Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) certification process. In addition to passing the examination, FPGEC applicants are required to have certain documents submitted from educational and licensure institutions that present their educational backgrounds and licensure and/or registration to practice pharmacy. Applicants must also pass the Test of English as a Foreign Language ™ (TOEFL®) and the Test of Spoken English™ (TSE®), or the TOEFL Internet-based Test (iBT). The FPGEC certificate allows foreign graduates to partially fulfill eligibility requirements for licensure in the 50 United States and the District of Columbia where the certification is recognized.

To prepare for the FPGEE, NABP recommends that applicants take the Pre-FPGEE®, the official FPGEE practice examination written and developed by NABP. This practice examination is designed to help familiarize applicants with the FPGEE by exhibiting the types of questions provided on the actual examination as well as providing a score estimate.

Additional information on the FPGEE as well as the Pre-FPGEE is available in the Examination Programs section on the NABP Web site at *www.nabp.net*.

## Updated 2009 Survey of Pharmacy Law Now Available

The NABP 2009 *Survey of Pharmacy Law*, providing a concise research source for key regulatory questions in pharmacy practice for all 50 states, the District of Columbia, and Puerto Rico, is now available.

The *Survey* updates, graciously provided by the state boards of pharmacy, consist of four sections including a state-by-state overview of organizational law, licensing law, drug law, and census data. Also, a new question in Section VII, "Issuance of Initial Pharmacist Licensure," asks whether or not states require criminal history record checks for initial licensure as a pharmacist.

To order the *Survey*, visit the NABP Web site at *www.nabp.net* and download an order form; the *Survey* costs $20.

All final-year pharmacy students receive the CD-ROM free of charge through the generous sponsorship of Purdue Pharma LP.

More information on the *Survey* is available by contacting customer service via phone at 847/391-4406 or via e-mail at custserv@nabp.net.

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- Take unused, unneeded, or expired prescription drugs out of their original containers and throw them in the trash.
- Mix prescription drugs with an undesirable substance, such as used coffee grounds or kitty litter, and put them in impermeable, nondescript containers, such as empty cans or sealable bags, to further ensure the drugs are not diverted.
- Flush prescription drugs down the toilet only if the label or accompanying patient information specifically instructs doing so.
- Take advantage of community pharmaceutical take-back programs that allow the public to bring unused drugs to a central location for proper disposal. Some communities have pharmaceutical take-back programs or community solid-waste programs that allow the public to bring unused drugs to a central location for proper disposal. Where these exist, they are a good way to dispose of unused pharmaceuticals.

**Food and Drug Administration advises that the following drugs be flushed down the toilet instead of thrown in the trash:**

- Actiq® (fentanyl citrate)
- Daytrana™ Transdermal Patch (methylphenidate)
- Duragesic® Transdermal System (fentanyl)
- OxyContin® Tablets (oxycodone)
- Avinza® Capsules (morphine sulfate)
- Baraclude® Tablets (entecavir)
- Reyataz® Capsules (atazanavir sulfate)
- Tequin Tablets (gatifoxacin)
- Zerit® for Oral Solution (stavudine)
- Meperidine HCl Tablets
- Percocet® (Oxycodone and Acetaminophen)
- Xyrem® (Sodium Oxybate)
- Fentora™ (fentanyl buccal tablet)

Note: Patients should always refer to printed material accompanying their medication for specific instructions.

## Readily Retrievable Prescription Information

Hard copies of all original prescriptions must be readily retrievable upon inspection. For example, e-prescribed prescriptions must be printed and placed in the prescription file; non-controls written on the same blank with controls should be referenced in non-control file; scanned prescriptions that are re-written must be attached to the original prescription; on-hold prescriptions that are assigned a new number when filled must be referenced to the original prescription number.

An inspector should always be able to find the original prescription, if it is appropriately documented in the prescription files.

## Section 40-43-86

(F) A prescription drug order must be issued for a legitimate medical purpose by a practitioner acting within the course of legitimate professional practice. The prescription drug order must be received at the pharmacy as it was originally transmitted. Each prescription drug order becomes part of a permanent record and must **be readily retrievable**. The institutional pharmacist must review the physician's drug order, or a direct copy, prior to dispensing any drug (except for emergency use). Electronically transmitted prescription drug orders shall meet these requirements.



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Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Larissa Doucette - Communications Manager

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

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