



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

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Published to promote voluntary compliance of pharmacy and drug law.

Pharmacist License Renewals

License renewal applications will be mailed prior to March 1, 2005, to every currently licensed pharmacist at his or her mailing address of record. The correctly completed renewal application, with all required fees and attachments, must be received by the South Carolina Board of Pharmacy office no later than April 1, 2005.

Do not send continuing education (CE) certificates to the Board office unless specifically requested to do so. The South Carolina Board of Pharmacy will not be responsible for any CE certificates unless they have been requested.

In order to prevent your application from being returned, please do the following:

- ◆ Read and follow all instructions.
- ◆ Sign and date the application.
- ◆ Include the proper fee of \$80 for applications received on or before April 1, 2005. A fee of \$130 must accompany applications received after April 1, 2005. If you have practiced after April 30, 2005, you may be assessed a civil penalty for practicing with a lapsed license.
- ◆ Applications submitted for renewal after April 30, 2005, must meet the renewal requirements and contain the appropriate fees and penalties. Applicants shall sign a pre-licensing agreement certifying that their license is subject to the right to impose sanction for unlicensed practice pursuant to §40-1-110 and §40-43-110(D). The following windows of time will be subject to additional penalties as listed below.

May 1-15, 2005	Additional \$100
May 16-31, 2005	Additional \$150
June 1-15, 2005	Additional \$200
June 16-30, 2005	Additional \$250
After July 1, 2005	Disciplinary Proceedings before the full Board of Pharmacy
- ◆ You must have a total of 15 CE hours. Six of these must be live and seven-and-one-half of this total must be in drug therapy or patient management. All must be Accreditation Council for Pharmacy Education or Continuing Medical Education Category I approved. All hours must be earned between January 1, 2003, and the date on which you submit your renewal. You must have your certificate in hand. If exempt from CE, proper documentation must be attached to the application.

Alert

All South Carolina pharmacists need to be aware and informed of the dangers associated with forming business affiliations or partnerships with Web-based companies that attempt to legitimize prescriptions by way of utilization of a duly licensed pharmacy for labeling and supplying medication. Partnerships are typically offered to independent pharmacies as an incentive to increase their volume and profit base by filling prescriptions provided via fax transmissions from the Web-based company. There have been violations in which medications were dispensed and, upon investigation, the prescriptions issued did not fulfill the legal requirements of the South Carolina Pharmacy Practice Act.

According to §40-43-30 (47) of the South Carolina Pharmacy Practice Act, a “prescription drug order” is defined as a lawful order from a practitioner for a drug or device for a specific patient, issued for a legitimate medical purpose within the prescriber’s course of legitimate practice and including orders derived from collaborative pharmacy practice.

§40-43-86 (F) (4) further states that [T]he pharmacist shall exercise professional judgment regarding the accuracy or authenticity of the transmitted prescription drug order consistent with existing federal or state laws and regulations.

Therefore, **do not** be deceived or coerced into participating with a Web-based company without contacting the Board to assist with verification and the legality of the site.

Facility Permit Renewals on the Horizon

Facility permit renewal applications will be mailed by the end of April 2005. If you are the permit holder and do not receive your permit renewal application, contact the Board office immediately. Applications for renewal must be postmarked before June 1, 2005, as required by §40-43-90(D) of the Pharmacy Practice Act. If you do not submit a renewal application, your existing permit will expire on June 30, 2005. You cannot legally operate without a permit.

If the renewal application is received after June 1, 2005, and does not have an earlier postmark, the Department of Labor, Licensing, and Regulation must assess a \$50 late fee for the special handling of the late application. Postage meter imprints are not acceptable as proof of mailing. It is recommended that you send your renewal applications via certified mail with return receipt requested, so that you will have proof of mailing by the deadline.

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The Effects of the Flu Vaccine Shortage

In early October 2004, Chiron Corporation, one of two major pharmaceutical manufacturers of influenza vaccine, informed the Centers for Disease Control and Prevention (CDC) that it would be unable to distribute its estimated 48 million doses of Fluvirin® in time for the 2004-05 flu season. The United Kingdom's Medicines and Healthcare products Regulatory Agency temporarily suspended Chiron's license for its Liverpool facility that was scheduled to produce Fluvirin for distribution throughout the United States.

During the 2003-04 flu season, approximately 87 million doses of influenza vaccine were administered. Before Chiron's announcement, it was expected that 100 million doses would be available during this season, with Aventis, the other major influenza vaccine (Fluzone®) producer, contributing 54 million doses. Aventis has indicated that it will be able to produce an additional 2.6 million doses of influenza vaccine by January 2005.

Shortly after this announcement CDC convened its Advisory Committee on Immunization Practices to issue recommendations to prioritize the existing supply of influenza vaccine. In summary, the CDC recommends that the following priority groups be given available doses first due to their increased risk of complications from influenza infection:

- ◆ Persons aged 65 years or older;
- ◆ Children six to 23 months of age;
- ◆ Residents of long-term care facilities and nursing homes;
- ◆ Persons two to 64 years of age with chronic medical conditions;
- ◆ Health care workers involved in direct patient care;
- ◆ Household contacts and out-of-home caregivers of children less than six months of age;
- ◆ Children and teenagers between the ages of six months and 18 years who are receiving aspirin therapy; and
- ◆ Pregnant women.

Although not appropriate for everyone, FluMist® (MedImmune), the intranasal influenza vaccine, may be a good alternative for healthy persons between the ages of five and 49. Unlike Fluvirin and Fluzone injectables, which are inactivated influenza vaccines, FluMist is a live attenuated virus, which, if administered to at-risk groups, particularly those with compromised immune systems, may in rare instances actually cause disease.

Other alternatives include antiviral medications, which may be used to prevent and treat influenza infection. The antiviral agents rimantadine, Tamiflu® (oseltamivir), and amantadine are Food and Drug Administration (FDA) approved for treatment and prophylaxis of influenza. Relenza® (zanamivir) is only approved for influenza treatment. To help minimize resistance, CDC currently encourages the use of amantadine or rimantadine for influenza prevention while using the other antivirals oseltamivir or zanamivir for treatment.

Although vaccination and other pharmacologic interventions are extremely beneficial, health care professionals should educate patients on practical measures that can be taken to prevent the spread of influenza. These include:

- ◆ Washing your hands frequently to avoid the spread of viruses and bacteria;
- ◆ Avoiding contact with people who may be sick;
- ◆ Cleaning telephones, door knobs, and other environmental surfaces with disinfecting agents to help prevent the spread of viruses and bacteria;
- ◆ Covering your mouth and nose when coughing or sneezing;

- ◆ Staying home from work and/or school when you are sick and limiting/eliminating contact with those who have compromised immune systems.

In late August 2004, US Department of Health and Human Services (HHS) Secretary Tommy G. Thompson released preliminary plans for a National Pandemic Influenza Preparedness Plan that details a national strategy to prepare for and respond to an influenza pandemic and provides action steps that should be taken at the national, state, and local levels during a pandemic. At press time, the draft plan was located at www.hhs.gov/nvpo/pandemic-plan. Pharmacists have become increasingly active in efforts to increase the public access to immunizations; according to National Association of Board's of Pharmacy® (NABP®) 2003-2004 *Survey of Pharmacy Law*, more than half of the states allow pharmacists to administer immunizations.

Because of the influenza vaccine shortage, many have expressed concerns about the possibility of counterfeit influenza vaccines. Pharmacies and health care institutions should only secure product from reputable resources and immediately report any suspect product. Also, many pharmacies have reported that the price of influenza injectable vaccines from some distributors has more than doubled since the shortage. In mid-October 2004, HHS Secretary Thompson urged the state attorneys general to prosecute those who were price gouging the cost of influenza vaccines.

For more information visit these Web sites:

FDA Flu Information – www.fda.gov/oc/opacom/hottopics/flu.html.

CDC Influenza Information (including vaccination information and Antiviral Medication Usage Guidelines) – www.cdc.gov/flu.

FDA Urges Consumer Education About Counterfeit Drugs

In an interim report, FDA's Anti-Counterfeiting Task Force stressed the importance of increasing awareness and education of stakeholders including the public concerning counterfeit drugs. The report called for increasing efforts of FDA and other government agencies to educate consumers and health care professionals on how to reduce the risk of obtaining counterfeit drugs before the event occurs; educating consumers and health care professionals on how to identify counterfeit drugs; and improving and coordinating FDA and industry messages and efforts to address and contain a counterfeit event. At press time, FDA had available on its Web site (www.fda.gov/cder/consumerinfo/counterfeit_all_resources.htm) public service announcements that can be printed for consumers as well as educational articles to inform the public.

One recent high-profile case concerned Viagra® (sildenafil citrate) that was dispensed from two pharmacies located in California. The counterfeit product closely resembled genuine Viagra tablets with respect to size, shape, color, and imprinting; however, the counterfeit drugs had subtle differences in tablet edging, film coating, imprinting font, and packaging. At press time, FDA, along with Pfizer, Inc, the legitimate manufacturer of Viagra, was analyzing the counterfeit product to determine its true composition and whether or not it posed any health risks; fortunately, no injuries had been reported. For comparative photos of the counterfeit drug and genuine Viagra, refer to Pfizer's "Dear Pharmacist" letter posted on the company's Web site at www.pfizer.com as well as FDA's distributed a press release that is now available at www.fda.gov.



Exactly one month after the counterfeit Viagra product was discovered, FDA expressed concern regarding counterfeit versions of the prescription drugs Zocor® (simvastatin) and carisoprodol, which were imported from Mexico by US citizens. Tests of these products revealed that the counterfeit Zocor, reportedly purchased at Mexican border-town pharmacies and sold under the name Zocor 40/mg (lot number K9784, expiration date November 2004, and lot number K9901, expiration date December 2006), did not contain any active ingredient. Likewise, the counterfeit carisoprodol 350/mg (lot number 68348A) test results indicated that the products differed significantly in potency when compared to the authentic product. FDA continues to investigate this matter and is working with Mexican authorities to ensure that further sale and importation of these products are halted. For more information on counterfeit Zocor, visit www.fda.gov/bbs/topics/ANSWERS/2004/ANS01303.html.



Diabetes or Alzheimer's Disease?

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.

Several reports of mix-ups have been reported in which the antidiabetic agent AMARYL® (glimepiride) had been dispensed to geriatric patients instead of the Alzheimer's Disease medication REMINYL® (galantamine). Each drug is available in a 4 mg tablet, although other tablet strengths are also available for each.

In one case, a 78-year-old woman with a history of Alzheimer's disease was admitted to the hospital with hypoglycemia (blood glucose on admission 27 mg/dL). A review of the medications she was taking at home revealed that her pharmacist dispensed Amaryl 4 mg, which she took twice daily instead of Reminyl 4 mg BID. In another case, an 89-year-old female received Amaryl instead of Reminyl for three days, eventually requiring hospitalization for treatment of severe hypoglycemia. A third patient received Amaryl instead of Reminyl while in the hospital, leading to severe hypoglycemia. All patients recovered with treatment. These events have been linked to poor prescriber handwriting and sound-alike, look-alike names. It is possible that prescriptions for Amaryl are more commonly encountered than those for Reminyl. Thus, confirmation bias (seeing that which is most familiar, while overlooking any disconfirming evidence) may lead pharmacists or nurses into "automatically" believing a Reminyl prescription is for Amaryl.

Obviously, accidental administration of Amaryl poses great danger to any patient, especially an older patient, who may be more sensitive to its hypoglycemic effects. Practitioners should be alerted to the potential for confusion between Amaryl and Reminyl. Prescribers should be reminded to indicate the medication's purpose on prescriptions. Consider building alerts about potential confusion into computer

order entry systems and/or adding reminder labels to pharmacy containers. Patients (or caregivers) should be educated about all of their medications so they are familiar with each product's name, purpose, and expected appearance. Most importantly, at all times pharmacists and nurses should confirm that patients are diabetic before dispensing or administering any antidiabetic medication, including Amaryl. FDA, Aventis (Amaryl), and Janssen Pharmaceutica Products LP (Reminyl) are aware of these reports and will be taking action to help reduce the potential for errors.

Medication Safety Videos Available Free

FDA's Center for Devices and Radiological Health has been producing a monthly series of patient safety videos available via the Internet. ISMP and FDA's Division of Medication Errors and Technical Support, Office of Drug Safety, has been cooperating in this effort. Access www.ismp.org/Pages/FDAVideos.htm for videos related to medication errors. See www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/viewbroadcasts.cfm for a complete list of all broadcasts.

2005 Survey of Pharmacy Law Now Available

NABP's 2005 Survey of Pharmacy Law CD-ROM is now available. Eight new questions were added to this year's Survey; topics include the formatting requirements of prescription pads, laws/regulations on the disposal of medications, and whether or not pharmacists are allowed to dispense emergency contraception without a prescription.

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 check or money order to NABP. The CD-ROM is provided free of charge to all final-year pharmacy students through a grant from GlaxoSmithKline. 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.

NABP Headquarters Moves to New Location

NABP has moved its Headquarters to 1600 Feehanville Drive, Mount Prospect, IL 60056. The new phone number is 847/391-4406 and the new fax number is 847/391-4502. All printed communications can be sent to the Feehanville Drive address. If you have any questions concerning the Association's new Headquarters, please contact the Customer Service Department at custserv@nabp.net or call 847/391-4406.

Register Now for NABP's 101st Annual Meeting

Register now for NABP's 101st Annual Meeting, May 21-24, 2005, at the Sheraton New Orleans Hotel, New Orleans, LA, so you can take advantage of the chance to earn up to five hours of continuing education (CE).

This year, CE sessions will focus on topics that fall under the Meeting's theme, "A Medley for Patient Safety: Accreditation, Self Assessment, Quality Care." Other events include the Educational Presentation Area and Poster Session, the President's Welcome Reception, NABP's annual business sessions, and the Annual Awards Dinner. In addition, you and your spouse or guest will have the opportunity to participate in a special recreational tour and the annual Fun Run/Walk.

For more information visit NABP's Web site at www.nabp.net, or contact NABP at 847/391-4406 or custserv@nabp.net.

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If the renewal application is not received by June 30, 2005, the facility will be assessed a penalty of \$10 a day until the permit is reinstated, plus the \$50 late fee and the new application fee. Depending upon the circumstances, the facility, the pharmacist-in-charge, and the pharmacists who practice in the pharmacy may be charged with violations of the practice act for operating without a permit pursuant to §40-43-83. Sanctions can include civil penalties, reprimands, or requirements for additional CE.

Board Updates Policy and Procedure #137

The Board of Pharmacy updated policy and procedure #137 at its November 2004 meeting regarding the implementation of the intent of United States Pharmacopeia (USP) Tests and Assays Chapter 797, Pharmaceutical Compounding – Sterile Preparations. A facility that is permitted by the Board to engage in sterile product compounding should meet the intent and guidelines of the USP by the permit renewal period beginning January 2006 by obtaining accreditation from an organization approved by the Board **and/or** giving evidence of personnel training, facility and equipment maintenance, and product testing and validation. Policies and procedures as well as logs and other documentation should be maintained by the facility to support compliance with the level of product compounding performed. In lieu of compliance by the above-mentioned date, a facility may propose a written plan of action for compliance and be subject to reinspection on an individual basis.

What is the Emergency Health Powers Act and What Does it Have to Do With Me?

In 2002 the General Assembly passed the Emergency Health Powers Act, found in Code §44-4-100 *et seq.* The legislation enables the state to respond to the threat of terrorist attacks or natural epidemics that might result in casualties that exceed the normal capacity of the health care system. Of particular interest to pharmacists, the Act:

- ◆ Requires pharmacists and other health care providers to report unusual or increased rates of prescription rates, types of prescriptions, or trends; the statute specifically lists prescriptions to treat fever, respiratory, or gastrointestinal complaints, but is not limited to those symptoms;
- ◆ Requires pharmacists to report unusual clusters of requests for information regarding over-the-counter medications to treat fever, respiratory, or gastrointestinal complaints;

- ◆ Authorizes licensing authorities to require qualified health care providers to assist in administering vaccinations;
- ◆ Authorizes the Department of Health and Environmental Control (DHEC) to collect inventories of available pharmaceuticals in health care facilities and in the distribution system and to ration or set priorities for dispensing pharmaceuticals determined to be in short supply; this includes possible price controls;
- ◆ Authorizes DHEC to obtain, store, and distribute antitoxins, serums, vaccines, immunizing agents, antibiotics, and similar pharmaceutical agents;
- ◆ Authorizes licensing authorities to waive licensing requirements and fees for out-of-state emergency health care providers; and
- ◆ Includes some “Good Samaritan” provisions regarding immunity from liability.

DHEC is working with the United States Centers for Disease Control and Prevention to plan for possible receipt and distribution of the Strategic National Stockpile of medicines and medical supplies that may be needed in a public health emergency.

DHEC has begun the process of promulgating a regulation to implement the Emergency Health Powers Act and is soliciting public comments. You may obtain additional information by contacting the Office of Public Health Preparedness at DHEC or by submitting comments to the Office of General Counsel, Attn: Samuel L. Finklea, South Carolina DHEC, 2600 Bull St, Columbia, SC 29201, or via e-mail at finklesl@dhec.sc.gov.

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The *South Carolina Board of Pharmacy News* is published by the South Carolina 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.

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