

May 2006



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

Kingstree Bldg, 110 Centerview Dr
PO Box 11927, Columbia, SC 29211-1927
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Published to promote voluntary compliance of pharmacy and drug law.

Congratulations to Board Appointee

The South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy would like to congratulate James R. Bradham, RPh, of Charleston, SC, on his recent reappointment to the Board by Governor Mark Sanford. His six-year term expires on June 30, 2011. Mr Bradham represents the First Congressional District and provides valuable expertise in hospital pharmacy practice. He heads up the Compounding Task Force, the Legislative Committee, Detention Center Committee, and the Federally Qualified Health Clinic Task Force of the Board. We would like to extend our gratitude to Mr Bradham for his continued hard work and commitment to the citizens of South Carolina and the profession of pharmacy.

Pharmacy Permit Renewals

The 2006 renewal forms were mailed out on or before May 1, 2006, to the last known address we have on file. The online renewal notice you receive will contain a **user identification (ID)** and **password** that will allow you access to the online renewal Web site. You will be charged an online convenience fee of \$1.25 (processing fee) in addition to regular renewal fees. The online renewal system has been enhanced for ease of use as well as for your convenience during the renewal process. If you choose not to renew your permit online, you may request a renewal form from the Board or print a renewal form from our Web site at www.llr.state.sc.us/pol/pharmacy. The completed form along with proper fees should then be mailed to the Board at Synergy Business Park, Kingstree Building, 100 Centerview Dr, Columbia, SC 29210. The permit renewal applications have been modified to require your Federal Identification Number for proper tracking of South Carolina facilities.

All applications must be received at the Board's office prior to June 1, 2006, or a \$50 late fee will be assessed. After June 30, 2006, the facility permit will lapse. Upon application for reinstatement, 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 continuing education (CE).

Congress Adopts the 'Combat Methamphetamine Epidemic Act of 2005'

This act was part of the legislation to reauthorize the United States Patriot Act (Public Law 109-177). The Combat Methamphetamine Epidemic Act of 2005 places **all** ephedrine, pseudoephedrine, or phenylpropanolamine products in a new federal Controlled Substances Act category of "scheduled listed chemical products." Drug

products that are listed in this new category may be marketed as a nonprescription drug; however, they are subject to sales restrictions, storage requirements, and record keeping requirements. President George W. Bush signed this legislation into law on March 9, 2006. The sales limits, blister pack, mail order restrictions, and behind the counter access requirements went into effect 30 days after President Bush signed the Act.

Requirements of the Act

- ◆ Limits daily retail sales to 3.6 grams per person per day.
- ◆ Limits 30-day retail purchases to 9 grams.
- ◆ Requires non-liquid forms to be sold in blister packs.
- ◆ Requires sellers to place the product behind the counter.
- ◆ Requires the sellers to maintain a written or electronic log of sales that identifies
 1. the product name;
 2. quantity sold;
 3. names and addresses of purchasers;
 4. dates and times of sales; and
 5. requires purchasers to present a photo ID and sign the logbook.

The log must be maintained for two years after the date of the last entry and privacy protections exist for information in the logs. The log must show a misrepresentation warning to the purchaser; warning must include notice of maximum fine and term of imprisonment. Retailers (for each location) must submit to the attorney general a certification that it is in compliance with the Act's requirements, that employees have been trained as to the Act's requirements, and that records relating to such training are maintained.

Mail order sellers must confirm the identity of the purchaser and are limited to a 7.5 grams per 30-day sales limit.

Penalties of the Act

For the following violations:

- ◆ Knowingly exceeding the daily sales limit, independent of consulting a logbook; or
- ◆ Selling a non-liquid product that is not in a blister package or unit dose package; or
- ◆ Not keeping affected products behind a counter or in a locked cabinet; or
- ◆ Not following log and recordkeeping requirements; or
- ◆ Not complying with privacy restrictions on the sales log; or
- ◆ Not requiring the purchaser to show an ID; or

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FDA Cautions Consumers About Filling US Prescriptions Abroad

Food and Drug Administration (FDA) issued a warning to health care professionals and consumers that filling their prescriptions abroad may have adverse health consequences due to the confusion with drug brand names that could inadvertently lead consumers to take the wrong medication for their condition. In an investigation, FDA has found that many foreign medications, although marketed under the same or similar-sounding brand names as those in the United States, contain different active ingredients than in the US. Taking a different active ingredient could potentially harm the user.

FDA found 105 US brand names that have foreign counterparts that look or sound so similar that consumers who fill such prescriptions abroad may receive a drug with the wrong active ingredient. For example, in the United Kingdom, Amyben[®], a brand name for a drug product containing amiodarone, used to treat abnormal heart rhythms, could be mistaken for Ambien[®], a US brand name for a sedative. Using Amyben instead of Ambien could have a serious adverse outcome. For more information on this topic visit www.fda.gov/oc/opacom/reports/confusingnames.html.

Safety Can Not be Sacrificed For Speed



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.

Problem: Typically, pharmacies have developed well-established methods for monitoring the accuracy of the dispensing process. But today, pharmacy work is increasingly stressful and these checks and balances can easily be strained beyond capacity. With an increasing number of prescriptions and a shortage of qualified pharmacists, conditions are ripe for potentially unsafe working conditions – long hours without breaks; multitasking between answering phones, overseeing other pharmacy staff, dispensing prescriptions, and counseling patients; and ever-increasing time spent attending to insurance issues. Inevitably, these conditions can increase the chance for dispensing errors.

One pharmacy knows this all too well after a five-year-old boy died as a result of an order entry and medication compounding error that was not caught by the usual verification process. In this case, imipramine was dispensed in a concentration five times greater than prescribed. Imipramine is a tricyclic antidepressant used to treat adults, but it is also used to treat childhood enuresis.

An extemporaneous solution was to be prepared at this pharmacy that specialized in compounded prescriptions since a liquid formulation was not commercially available. A pharmacy technician incorrectly entered the concentration of the prescribed solution into the computer as **50 mg/mL** instead of **50 mg/5 mL**, along with the prescribed directions to give 2 tsp at bedtime. He then proceeded to prepare the solution using the incorrect concentration on the label rather than the concentration indicated on the prescription. When the compound was completed, the technician placed it in a holding area to await a pharmacist's verification. At this time, one of the two pharmacists on duty was at lunch and the high workload of the pharmacy made it difficult for the pharmacist to check the prescription right away. When the child's mother returned to pick up the prescription, the cash register clerk retrieved the prescription from the holding area without telling a pharmacist, and gave it to the mother, unaware that it had not yet been checked. At bedtime, the mother administered 2 tsp of the drug (500 mg instead of the intended 100 mg) to the child. When she went to wake him the next morning, the child was dead. An autopsy confirmed imipramine poisoning.

There are many factors that contributed to this error including inaccurate order entry and issues related to high workload. However, a critical breakdown in safety processes occurred when the cash register clerk took the prescription from the pharmacy holding area (to prevent the mother from waiting any longer for the prescription), thereby circumventing the usual pharmacist verification process.

While this error underscores a growing problem in health care, the problem was clearly evident to this pharmacy owner – even a year before the error occurred. When interviewed for an article that appeared in a national publication, he vented his frustrations about the scant attention paid in our society to pharmacist workload difficulties faced in today's health care environment. On the day of the interview, 49 prescriptions were in the process of being prepared and about a dozen patients were standing in line or wandering around the store waiting for prescriptions. Yet this was a slow day. The owner also said that, while managed care had reduced profits considerably over the past several years, prescription volume had increased 50% (at the time of the error, the pharmacy was dispensing about 10,000 prescriptions per month versus 7,000 per month during the prior year, without an increase in staff) and medication regimens and drug interactions were more complex. To overcome these barriers, the owner added private consultation areas for patient counseling; installed a \$175,000 robot that accurately dispenses the 200 most common drugs; and diversified sales to offset full-time pharmacists' salaries. But these efforts could not have prevented this tragic fatal error that circumvented the normal safety processes.

Safe Practice Recommendations: The environment and demands placed on health professionals significantly affect their ability to provide safe health care services. While technology such as robots can help, overstressed professionals cannot consistently perform at the maximum level of safety. Therefore, it is important that the public and health care leadership understand this problem so they can be more open to tradeoffs, such as working



with one patient at a time and incurring longer turnaround times, which are necessary to enhance patient safety. With a shortage of qualified professionals, we need to demand more rapid adoption of computerized prescribing to reduce time spent with prescription transcription. We should identify the biggest distractions that occur in our workplaces and eliminate or reduce the source by batching common interruptions and reorganizing work areas. Staff members need to be properly trained to understand safety procedures that are in place and know the limits of their specific duties. Fail-safe processes to ensure an independent double check before dispensing medications and performing other critical processes are a must. The pharmacy where this error occurred now requires two pharmacists to check every prescription. Unfortunately, this level of vigilance is typical after a patient has been harmed from an error. In other pharmacies, especially where there is only one pharmacist on duty, technicians may be involved in the double-check process.

A few other strategies can be used to prevent similar errors:

- ◆ Have one person perform order entry and a different person prepare the prescription, if possible, to add an independent validation of the order entry process.
- ◆ Do not prepare prescriptions using only the computer-generated label, as order entry may have been incorrect.
- ◆ Ensure that the original prescription, computer-generated label, prepared product, and manufacturer's product(s) remain together throughout the preparation process.
- ◆ Verify dispensing accuracy by comparing the original prescription with the labeled patient product and the manufacturer's product(s) used.

NIH Develops Community Drug Alert Bulletin

The National Institute on Drug Abuse, as part of the National Institutes of Health (NIH), has developed a new Community Drug Alert Bulletin that addresses the latest scientific research on the non-medical use of prescription drugs of abuse and addiction.

This bulletin is geared toward parents, teachers, counselors, school nurses, and health professionals who are associated with those at risk from prescription drug abuse for non-medical purposes. It summarizes the growing problem in the US and the trend of non-medical use of prescription drugs. For more information on this bulletin visit www.nida.nih.gov/PrescripAlert/index.html.

Implementation of the Anabolic Steroid Control Act of 2004

According to the December 16, 2005 *Federal Register*, effective January 20, 2005, the Anabolic Steroid Control Act of 2004 amended the Controlled Substances Act (CSA) and replaced the existing definition of "anabolic steroid" with a new definition. This new definition changed the basis for all future administrative scheduling actions relating to the control of the anabolic steroids as Schedule III controlled substances (CS) by eliminating the requirement to prove muscle growth. Also, the Act lists 59 substances as being anabolic steroids; these substances and their salts, esters, and ethers are Schedule III CS. The Act also revised the language of the CSA requiring exclusion of certain over-the-counter products from regulation as CS.

According to the House Report, the purpose of the Act is "to prevent the abuse of steroids by professional athletes. It will also address the widespread use of steroids and steroid precursors by college, high school, and even middle school students."

The changes to the definition include the following:

- ◆ Correction of the listing of steroid names resulting from the passage of the Anabolic Steroid Control Act of 1990.
- ◆ Replacement of the list of 23 steroids with a list of 59 steroids, including both intrinsically active steroids as well as steroid metabolic precursors.
- ◆ Automatic scheduling of the salts, esters, and ethers of Schedule III anabolic steroids without the need to prove that these salts, esters, or ethers promote muscle growth.
- ◆ Removal of the automatic scheduling of isomers of steroids listed as Schedule III anabolic steroids.
- ◆ Addition of dehydroepiandrosterone to the list of excluded substances.

FDA Unveils New Package Insert Format

On January 18, 2006, FDA unveiled a major revision to the format of prescription drug information, commonly called the package insert, which will give health care professionals clear and concise prescribing information. This new format was developed in order to manage the risks of medication use and reduce medical errors; the new package insert will provide the most up-to-date information in an easy-to-read format. This new format will also make prescription information more accessible for use with electronic prescribing tools and other electronic information resources.

Revised for the first time in more than 25 years, the new format requires that the prescription information for new and recently approved products meet specific graphical requirements and includes the reorganization of critical information so physicians can find the information they need quickly. Some of the more important changes include:

- ◆ A new section called *Highlights* to provide immediate access to the most important prescribing information about benefits and risks.
- ◆ A table of contents for easy reference to detailed safety and efficacy information.
- ◆ The date of initial product approval, making it easier to determine how long a product has been on the market.
- ◆ A toll-free number and Internet reporting information for suspected adverse events to encourage more widespread reporting of suspected side effects.

This new format will be integrated into FDA's other e-Health initiatives and standards-settings through a variety of ongoing initiatives at FDA. For more information please visit www.fda.gov/cder/regulatory/physLabel/default.htm.

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- ◆ Not complying with employee training requirements; or
- ◆ Not complying with self-certification requirements; or
- ◆ To refuse to provide sales log information to law enforcement authorities.

The penalties are:

- ◆ Civil penalty of up to \$25,000;
- ◆ If committed knowingly, then imprisonment of up to one year in addition to a fine to be determined by existing federal criminal laws;
- ◆ If committed after a prior conviction of the Controlled Substances Act, then imprisonment of up to two years in addition to a fine to be determined by existing federal criminal laws; and
- ◆ A retailer (including pharmacy) or distributor may be prohibited from selling any scheduled listed chemical products for any violation above, except for refusal to provide sales log information to law enforcement authorities.

Please familiarize yourself with these requirements since most have been in effect since April 8, 2006.

Community Pharmacy Technician Certificate Web-CT (Online) Program

An Internet-based online Community Pharmacy Technician Certificate program will be offered through the Airport Campus of Midlands Technical College beginning summer semester 2006.

The program will be two semesters with the summer semester classes beginning May 22, 2006, and running until August 4, 2006. Fall semester classes will begin August 21, 2006, and will run until December 4, 2006. A program orientation session will be scheduled on the Airport Campus prior to the beginning of summer semester. Attendance at orientation will be mandatory.

Application to the Community Pharmacy Technician Certificate Program:

1. Complete an application for Midlands Technical College listing Community Pharmacy Technician Certificate as the program of study. Applications may be completed at the Airport or Beltline Campuses or online at www.midlandstech.edu.
2. Schedule placement testing (all students entering the college are tested or they may provide test scores, SAT, ACT, etc).
3. Requested copies of transcripts (high-school and college) sent to Midlands.
4. Apply for Financial Aid or Lottery Tuition Assistance when accepted to the college.

5. Interview with the director of the Pharmacy Technician Program when steps 1 through 3 are completed and admission to the college has been granted.

Program Admission Requirements:

1. Applicant must be a high school graduate or equivalent. (Recommend high school or college credits in mathematics and science, eg, algebra, biology, chemistry).
2. Recommend typing skills.
3. Current First Aid and cardiopulmonary resuscitation certification at time of entry.
4. Emotional and physical ability to carry out normal pharmacy activities (to include lifting, stretching, and standing for long periods).
5. Physical examination by a physician and the completion of a personal health form.
6. South Carolina Law Enforcement Division record check.

Program Costs:

	Per Semester	Per Year
Tuition	Approximately \$1,368	\$2,736
Student Fee	\$50	\$100
Pharmacy textbooks		\$250
A&P and Med Term		\$220 Additional
Arm Patch		\$10
Lab Jacket		\$35+
Malpractice Insurance		\$6
Technology Lapel Pin		\$40-\$170

Clinical experience will be arranged within a community retail pharmacy in a student's home community.

All lecture material and assignments will be done online. Testing will be done online, which will require the student to take monitored and proctored tests at the host college testing center.

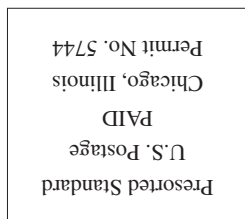
To apply to this program, visit our Web site at www.midlandstech.edu.

If you have any questions, please contact Kevin Eisenhour, Director, Pharmacy Technician Program, Midlands Technical College, PO Box 2408, Columbia, SC 29202. Office Phone: 803/822-3591.

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National Association of Boards of Pharmacy Foundation, Inc
1600 Feehanville Drive
Mount Prospect, IL 60056
SOUTH CAROLINA DEPARTMENT OF LABOR,
& REGULATION – BOARD OF PHARMACY