

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.

Biennial Renewal of Facility Permits and Pharmacy Technician Registrations

In an effort to streamline licensing procedures to bring fees more in line with operating costs, the South Carolina Department of Labor, Licensing, and Regulation and the Board of Pharmacy are moving toward biennial renewal of facility permits and pharmacy technician registrations. The 2009 renewal notices were mailed to you on or about April 1. We have enhanced our 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. 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.

All facility permit renewal applications must be received at the Board's office prior to June 1, 2009, or a \$50 late fee will be assessed. After June 30, 2009, the facility permit will lapse. Upon application for reinstatement, the facility will be assessed a penalty of \$10, plus the \$50 late fee and the new application fee. Operating with a lapsed permit may result in disciplinary action. Once the facility permits are renewed, they will not expire until June 30, 2011.

Pharmacy technician renewal applications need to be received in the Board office by June 1, 2009. Pharmacy technicians who do not renew by June 30, 2009, will be assessed penalties and shall not work as pharmacy technicians until a 2009-2011 registration is in hand or disciplinary action may result. Once the pharmacy technician registrations are renewed, they will not expire until June 30, 2011.

Continuing education requirements will be adjusted accordingly.

Policy and Procedure #146

At its March 2009 meeting, the Board approved the following guidelines for 30-minute meal breaks.

If a permitted facility allows their pharmacist to participate in a 30-minute meal break the following guidelines must be in place.

1. Policies and procedures must be present which define the approval and eligibility, and procedures on how to handle before, during, and after the 30-minute meal break.
2. Pharmacist must be in the permitted facility and have a sign posted that the pharmacist is on break.
3. The permitted facility should attempt to have the break occur at a consistent time each day and proper notice given to the public.
4. In permitted facilities with overlapping pharmacists, breaks should be taken while other pharmacist coverage is available.
5. Pharmacist must be available to handle any emergency situations which may arise.

6. Pursuant to the Board of Pharmacy, technicians may perform the following duties while a pharmacist is on break:
 - ◆ Assemble prescriptions to be checked by the pharmacist when the break is over.
 - ◆ Provide prescriptions to the patients for pick up that have been previously prepared and checked by a pharmacist. A log must be completed for all transactions; new prescriptions and refills that occur while the pharmacist is on break.
 - ◆ Receive and assemble prescriptions. The pharmacist must check any prescription(s) before it goes to the patient pursuant to the Board's practice act.

Note: Any Drug Utilization Review messages must be reviewed and resolved by the pharmacist.

7. When requested by the patient, the pharmacist must call the patient within a reasonable timeframe after the prescription is picked up to review any counseling issues that may be appropriate for any prescriptions sold in the absence of a pharmacist.

There should be adequate training of all pharmacy personnel on how to handle 30-minute meal break coverage.

Compliance Tips Electronic Prescription Requirements

Since the passing of Electronic Prescription Processing Section 44-117-310, there has been confusion concerning what is required by the pharmacy and transmitters.

Information needed for electronic prescriptions:

1. A valid practitioner/patient relationship must exist
2. Prescription must identify the transmitter's phone number, the time and date of transmission, and the pharmacy intended to receive the transmission
3. Prescription must be transmitted to the pharmacy of the patient's choice
4. Prescription must have the practitioner's electronic or digital signature or key code (must have an identification number or code to identify the practitioner – cannot just state "Electronically signed by . . .")
5. Prescription may be sent computer to computer or computer to facsimile (may not have two lines, but must have designation for brand or generic substitution)
6. If an electronic prescription is printed out and given to the patient, **it must possess an original handwritten signature**
7. Electronic prescriptions must be printed out for the prescription files, which provides all required information in 2, 4, and 5
8. Routing companies must be registered with the South Carolina Board of Pharmacy

continued on page 4



NABP Seeking Pharmacists in All Practice Areas to Take Survey

The expertise of pharmacists in all areas of pharmacy practice is needed for an online survey NABP is conducting as part of a full pharmacy practice analysis. The survey, which is available at www.zoomerang.com/Survey/?p=WEB2297C9ZRC3F, will run from April 1 to June 30, 2009. Survey results will furnish data necessary to update and validate the current North American Pharmacist Licensure Examination® (NAPLEX®) competency statements, which are scheduled to be revised and implemented into the 2010 blueprint.

NABP conducts a pharmacy practice analysis at least every five years in accordance with standard testing industry examination development and revision guidelines. The analysis allows NABP to ensure that the NAPLEX competencies are in line with the existing pharmacy practice standards and that they accurately reflect the current knowledge, skills, and abilities of entry-level pharmacists seeking licensure. Questions may be directed to custserv@nabp.net or 847/391-4406.

Teen Abuse of Prescription Medications: Curtailing a Growing and Dangerous Trend

Teen-targeted, antidrug campaigns have shifted focus to tackle the current culprit in teen drug abuse: prescription medications. The nonprofit Partnership for a Drug-Free America (Partnership), and government agencies such as the Office of National Drug Control Policy (ONDCP) are using Web sites and televised public service announcements to educate parents and teens about the dangers of prescription drug abuse as well as prevention strategies. In support of such efforts, the National Association of Boards of Pharmacy® (NABP®) is taking steps to raise awareness among pharmacy stakeholders about the urgency of the issue, the benefits of prevention counseling for parents and teens, and support of local medication disposal programs.

A Trend with Deadly Consequences

The teen prescription drug abuse trend demands an assertive approach, as the Centers for Disease Control and Prevention (CDC) indicates that unintentional drug poisoning from misuse of prescription drugs is now the second leading cause of accidental death in the United States. Further, according to the Drug Abuse Warning Network, emergency room visits for prescription medication abuse and “street drugs” are almost equal. Substance Abuse and Mental Health Services Administration (SAMHSA) studies reveal that more teens are trying prescription medications in order to “get high” than marijuana.

To complicate matters, a study done by the Partnership suggests that prescription drugs are not just replacing illicit drugs but instead appear to be an intermediate step in drug use. As one survey participant stated, “[T]aking pills made me much more open to taking x [ecstasy]. At a certain point, it just became another pill.”

Prescription Drugs of Choice for Teens

Pain relievers such as Vicodin® and OxyContin®, stimulants such as Adderall® and Ritalin®, and tranquilizers such as Xanax® and Valium® are the prescription medications most frequently abused by teenagers, the Partnership finds.

Putting the problem in perspective, SAMHSA studies from 2007 show that 2.1 million adolescents age 12 or older tried prescription medications for nonmedical uses – the same number that tried mari-

juana. Tranquilizers (1.2 million teens), cocaine (0.9 million teens), ecstasy (0.8 million teens), inhalants (0.8 million teens), and stimulants (0.6 million teens) were the next drugs most frequently chosen by teens for first time use. SAMHSA reports that, every day, 2,500 youths (age 12 to 17) abuse a prescription pain reliever for the first time. Among teens who have abused painkillers, nearly one-fifth (18%) used them at least weekly in the past year.

Teens are also abusing over-the-counter products such as cough/cold medications. According to a SAMHSA study, 3.1 million people aged 12 to 25 had tried cough or cold medications to get high in their lifetime, and almost 1 million had done so in 2005.

Why Teens Choose Prescription Medications

In surveys conducted by the Partnership, teens reported that they used prescription drugs to help them deal with problems, manage their lives, lower stress, and enhance performance, as well as to get high.

According to ONDCP’s 2008 report, *Prescription for Danger: A Report on the Troubling Trend of Prescription and Over-the-Counter Drug Abuse Among the Nation’s Teens*, teens think that using prescription medications to manage stress or get high is safer than using street drugs. Further, prescription medications are more easily available to teens than illicit drugs such as cocaine or ecstasy. Teens obtain medications from the medicine cabinet at home, through friends, or at friends’ homes.

While prescription drugs may be more readily accessible for teens, large numbers are combining these medications with alcohol and/or illicit drugs. For example, 49% of teens who abused painkillers reported using two or more other drugs, including alcohol (81%) and marijuana (58%), ONDCP reports. Further, the report notes, poisonings as a result of combining prescription and over-the-counter drugs have risen drastically.

Stemming the Growth of Prescription Drug Abuse

In response to this growing problem, organizations and government agencies recommend educating both parents and teens about the dangers of prescription drug abuse, and modifying and encouraging the use of prescription medication disposal programs.

At its 104th Annual Meeting in May 2008, NABP passed a resolution that stipulates use of its newsletter programs to keep pharmacists and other constituents informed about the urgent issue of teen prescription drug abuse, so that they in turn can help to provide parents and teens with current prevention information. Such educational efforts are vital, as the Partnership reports that most parents do not realize that teens are intentionally abusing medications to get high, and that they think their teens are not vulnerable to prescription drug abuse. Further, the Partnership finds that, like many teens, parents tend to think that teen abuse of prescription medications is safer than teen abuse of street drugs.

Organizations such as the Partnership aim to educate parents and teens directly, informing them about the abuse trend, and emphasizing the necessity of using prescription medications appropriately.

Knowledge of this information is important to pharmacists since they are in an excellent position to counsel parents on teen drug abuse when dispensing prescriptions with high abuse potential.

Phil Bauer of the Partnership stated in his presentation at the NABP 104th Annual Meeting: “We need to reach out and empower parents, give them the information they need. Parents talking to kids reduces drug use by 50%.” Similar to past drug prevention programs that



focused on illicit drugs, Bauer and the Partnership encourage parents to communicate with their kids about prescription drug abuse and its dangers. Likewise, ONDCP reports that when parents express strong disapproval of drug abuse, teens are much less likely to adopt this dangerous behavior.

Another immediate step parents can take, the Partnership advises, is safeguarding the medications kept in their homes. Safeguarding involves properly disposing of unused and expired medications, and taking an inventory of all current medications. Further, parents can keep medications stored in an area that is not readily accessible to teens or their friends.

To raise awareness among families and the public, the Partnership, along with ONDCP, launched a media campaign using their Web sites as well as televised public service announcements aired during the 2008 Super Bowl. The Partnership Web site provides a list of facts parents can stress to teens. The Web site states: "The Partnership is urging parents, both through this new campaign and through our online resources and information to learn about this serious problem, share the information with their teens, and take action to prevent teens from accessing these medications at home."

More information and resources are available on the Partnership Web site at www.drugfree.org.

Health Care Consumers: Essential Partners in Safe Medication Use



This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes 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 risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Edition by visiting www.ismp.org. ISMP is a Federally Certified Patient Safety Organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also a Food and Drug Administration (FDA) MedWatch partner. Call 1-800-FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program (MERP) or report online at www.ismp.org. ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

A study in the September 10, 2007 *Archives of Internal Medicine* found that a significant percentage of American consumers may not be using their medications safely.

Between 1998 and 2005 alone, there was a 360% increase in deaths attributed to consumers using medications incorrectly at home (not involving alcohol or street drugs).

Proactive communication between pharmacists and patients is a major way to reduce the risk of medication errors.

However, there are barriers to patients communicating with pharmacists about the drugs they are taking, including limited time for speaking with patients and lack of appropriate written materials.

Pharmacists should explore ways to make suitable written materials on medications readily available. Be sure to seek feedback from patients (eg, through focus groups and targeted satisfaction survey questions) to ensure that written materials effectively communicate the most important information.

Management support for widespread education is essential to ensure effective use of electronic resources as well as dedicated time to talk with patients.

Many pharmacists assume that their patients can read, understand, and act on instructions on medication labels and in medication information pamphlets. But although 90 million Americans read below the 5th grade level, 98% of the medication information sheets accompanying dispensed prescriptions are written at a 9th to 12th grade level or higher.

Poor health literacy can lead to consumers misusing and making mistakes with their medications. Adults with low health literacy:

- ◆ Are less likely to adhere to prescribed treatment and self-care regimens
- ◆ Make more medication or treatment errors

Children are particularly vulnerable to medication misuse. One study has demonstrated that parents give their children an incorrect dose of over-the-counter fever medicine 47% of the time. Other recent studies have shown that educating parents on how to measure and administer the correct dose of medication for their children can prevent serious errors.

When dispensing pediatric medication, involve the child's parents and demonstrate correct measurement and administration techniques when possible. Emphasize the importance of using an appropriate measuring device (the original product dropper or dosing cup, or proper type of syringe), not a household spoon.

The Internet has opened a whole new avenue for consumers to obtain information on how to use their medications. Americans spend a large portion of time online searching for advice about health and safety. According to the 2007 *Preventing Medication Errors*, the percentage of adults who have sought health information online grew from 27% (54 million) in 1998 to 53% (117 million) in 2005.

But the report found that while there is an abundance of Internet-based health information, the quality of that information is variable.

ISMP maintains links to leading patient safety entities and information on its Web site, www.ismp.org, and recently launched a consumer-focused Web site that provides even more specific medication safety information. Visit the new site at www.ConsumerMedSafety.org. ISMP allows and encourages all state board Web sites to link to this new consumer patient safety Web site.

FDA Expands Warning to Consumers about Tainted Weight Loss Pills

On January 8, 2009, FDA expanded its nationwide alert to consumers about tainted weight loss pills that contain undeclared, active pharmaceutical ingredients. On December 22, 2008, FDA warned consumers not to purchase or consume 28 different products marketed for weight loss. Since that time, FDA analysis has identified 41 more tainted weight loss products that may put consumers' health at risk. The complete list of drugs is available on the FDA Web site.

continued from page 1

9. Prescriptions for control drugs in Schedules II through V cannot be transmitted electronically
10. If all information is not on the transmitted prescription, the practitioner must be called for verification and documentation must be made on the prescription of changes and the identification of the pharmacist responsible.
11. Rubber stamps of licensed practitioner's signatures are **not** acceptable at any time.

Prescriptions for Oxygen Therapy and Concentrators

An **oxygen concentrator** is a device that is dispensed per a doctor's order. There is no need for a new prescription until it is necessary to provide a new or different type of concentrator. Documentation for the dispensed device must be kept on file for two (2) years.

Oxygen is considered a legend drug and must be dispensed by prescription. An ongoing prescription is valid for no longer than two (2) years to continue to provide tanks or refill tanks of oxygen. A new prescription is needed every two (2) years to meet statute. It would be advisable to have a signed document of notification from the patient or caregiver that a new prescription will be needed close to the time (possibly sixty [60] days) that a new prescription will be needed.

Policies and procedures should be in place to cover the discharge of a patient. You may want to check with your legal advisors to discuss liability concerns of removing concentrators or tanks already dispensed.

Medco Over-the-Counter (OTC) Card

Pharmacies have been receiving Medco Care Improvement Plus OTC Cards that instruct them to process through TelePaid. The plan states that a prescription is not required. Some pharmacies have been processing OTC products using the pharmacy's National Provider Identifier number and/or using "Dr OTC" as the prescriber. It is not acceptable to make a prescription without a practitioner's authorization and it could cause issues with the Department of Revenue; therefore, the pharmacist would need to contact the practitioner to receive a valid prescription for the OTC medication.

According to §40-43-86(U) of the South Carolina Pharmacy Practice Act, "Nonprescription drugs may be sold by any retailer in their original, unbroken prepackaged containers and no rule or regulation shall be adopted by the Board of Pharmacy which shall require the sale of nonprescription drugs by a licensed pharmacist or in a pharmacy. **However, nonprescription drugs may also be dispensed and profiled by pharmacists pursuant to a practitioner's prescription, and when dispensed in this manner by a pharmacist, the drug must be treated in all respects as a prescription drug and all prescription drug counseling and labeling requirements shall apply.**"

The South Carolina Board of Pharmacy will send a letter to Medco informing them that it is not acceptable to make prescriptions in South Carolina for billing purposes without a valid prescription from a practitioner.

Note: OTC Cards provided by any third party would also have to have a valid prescription from a practitioner in order for the entity to bill.

Policy and Procedure for Non-Dispensing Drug Outlet Permits

Most of the non-dispensing drug outlet permits with the exception of wholesaler and repackagers need a policy and procedure that covers the handling of sterile products. These facilities are drawing up sterile medications from single and multi-dose vials; therefore, they must meet the United States Pharmacopeia (USP) Chapter 797 guidelines. Consultant pharmacists shall add to their policies and procedures the sections for **immediate-use compounded sterile preparations (CSPs)** and **single and multi-dose containers**. For example, a multi-dose vial should have a 28-day expiration date, or unless otherwise specified by the manufacturer, put on the vial when it is initially opened.

Gloved Finger Tip Sampling

Upon inspections of facilities that are compounding sterile products, most facilities have not done the gloved finger tip sampling. This procedure is done to evaluate proper hand washing and glove techniques. The procedure shall be done three times initially, and at least once annually for low-and medium-risk level CSPs and semiannually for personnel who prepare high-risk CSPs. There is a section in USP Chapter 797 under Competency Evaluation of Garbing and Aseptic Work Practice that will give detailed instructions.

Information from the March 2009 Pharmacy Board Meeting

- ◆ The June 24-25, 2009 Board Meeting location has been changed from Myrtle Beach, SC to Columbia, SC in Room 108 of the Department of Labor, Licensing, and Regulation Kingstree Building.
- ◆ Policy and Procedure #133 on OTC compounding is being deleted due to Food and Drug Administration regulations and USP Chapter 795 standards that would require a physician/patient/pharmacist relationship with a prescription.
- ◆ The Department of Labor, Licensing, and Regulation Web site has been revised with the Board of Pharmacy listed under the **Office of Health and Medical** for pharmacists, technicians, and interns, **and the Office of Building and Business Services** for permits.

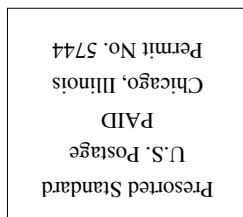
Page 4 – May 2009

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.

Lee Ann F. Bundrick, RPh, Administrator - State News Editor

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
SOUTH CAROLINA DEPARTMENT OF LABOR,
LICENSING, & REGULATION – BOARD OF PHARMACY