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

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Pharmacy Technician Renewals

The 2013 renewal notices were mailed to pharmacy technicians on or about April 15. The renewal notice included a **user ID** and **password** to allow you to access the online renewal Web site. **If you are a state-certified pharmacy technician, you must mail a copy of your current national certificate from the Pharmacy Technician Certification Board to the South Carolina Department of Labor, Licensing, & Regulation – Board of Pharmacy.**

If you choose not to renew online, you may download the renewal application and renew by mailing the completed form and proper fees to the Board office. **Applications must be received in the Board office by June 1, 2013. Pharmacy technicians who do not renew before midnight on June 30, 2013, will be assessed penalties. Pharmacy technicians may not work until a 2013-2014 registration is received and renewed, or disciplinary action may result.** If you do not renew online, please document the date the application is mailed. **The Board recommends sending paper renewal applications via certified mail with a return receipt requested.**

Continuing Education Reporting for Pharmacy Technicians

In order to renew online, you must indicate that you have completed the required 10 hours of Accreditation Council for Pharmacy Education (ACPE)-accredited or continuing medical education (CME) Category I continuing education (CE) each year. Of the 10 hours, a minimum of four hours must be "live" hours. CE must be taken **before** renewing a registration each year.

Please note:

- **There are no exemptions to the CE requirement for technicians.**
- Technicians may take CE that is designated for pharmacists (P) or technicians (T).
- Use the ACPE universal program number (UPN) to determine if CE is live (L), home (H), or combination (C). Example: Live CE will have an "L" in the UPN, eg, 430-000-092-021-L01.
- All CME Category I hours are live hours.
- Hours completed in excess of the requirements may be carried forward in the next registration year but may not be carried forward for more than one registration year. It is the responsibility of the technician to keep up with excess hours that can be forwarded to the next registration year.

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 demonstrate that you completed the CE requirements or if the required CE is dated after your renewal is received in the Board office.

Facility Permit Renewals

The facility permit renewal notices and forms were mailed out in mid-April 2013 to the last known address on file in the Board office. If you are a permit holder and have not received your permit renewal application, contact the Board office immediately. The renewal notice you receive will contain a **user ID** and **password** to allow you access to the online renewal Web site.

If you choose not to renew your permit online, you may download a renewal form from the Board's Web site. Mail the completed form, along with proper fees, to the Board at PO Box 11927, Columbia, SC 29211. All applications must be received at the Board's office prior to June 1, 2013, or a $50 late fee will be assessed. After June 30, 2013, 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 a new application fee. Depending upon the circumstances, the facility, the pharmacist-in-charge, and/or the pharmacists who practice in the pharmacy may be charged with violations of the South Carolina

Continued on page 4

FDA Issues New Guidelines for Sleep Aids Containing Zolpidem

Food and Drug Administration (FDA) has issued new dosing recommendations for sleep aids containing zolpidem. The new recommendations are based upon new data that shows that when taken at night, blood levels of zolpidem remain high enough in the morning to impair activities that require alertness, such as driving. The new guidelines halve the dosage for women because the new data showed that their bodies take longer to eliminate the drug.

FDA urges drug manufacturers and health care providers to follow the new dosing instructions, which apply to brand name and generic drugs containing zolpidem:

- Ambien®, Edluar™, and Zolpimist®: 5 mg for women, 5 mg or 10 mg for men
- Ambien CR®: 6.25 mg for women, 6.25 mg or 12.5 mg for men

Additionally, manufacturers of these drugs have been instructed to follow the new guidelines and print new patient information drug labels containing the new recommendations.

The recommended doses of Intermezzo®, a lower dose zolpidem product approved for middle-of-the-night awakenings, are not changing. At the time of Intermezzo's approval in November 2011, the label already recommended a lower dosage for women than for men. Additional details are available in an FDA Drug Safety Communication, available at *www.fda.gov/Drugs/DrugSafety/ucm334033.htm.*

What is the National Medication Error Rate? What Standards Are Available for Benchmarking?

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 Care 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 an FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program 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 national or other regional medication error rate does not exist. It is not possible to establish a national medication error rate or set a benchmark for medication error rates. Each pharmacy organization is different. The rates that are tracked are a measure of the number of **reports** at a given organization, not the actual number of **events** or the quality of the care given. Most systems for measuring medication errors rely on voluntary reporting of errors and near-miss events. Studies have shown that even in good systems, voluntary reporting only captures the "tip of the iceberg." For this reason, counting **reported** errors yields limited information about how safe a pharmacy actually is. It is very possible that a pharmacy organization with a good reporting system, and thus what appears to be a high error "rate," may have a safer system.

The National Coordinating Council for Medication Error Reporting and Prevention published a statement refuting the use of medication error rates. The statement, which is posted on the council's Web site (*www.nccmerp.org*), states the "Use of medication error rates to compare health care organizations is of no value." The council has taken this position for the following reasons:

- Differences in **culture** among health care organizations can lead to significant differences in the level of reporting of medication errors.
- Differences in the **definition** of a medication error among health care organizations can lead to significant differences in the reporting and classification of medication errors.
- Differences in the **patient populations** served by various health care organizations can lead to significant differences in the number and severity of medication errors occurring among organizations.
- Differences in the **type(s) of reporting and detection systems** for medication errors among health care organizations can lead to significant differences in the number of medication errors recorded.

According to the statement, the council believes that there are no acceptable incidence rates for medication errors. The goal of every health care organization should be to continually improve systems to prevent harm to patients due to medication errors. Pharmacies should monitor actual and potential medication errors that occur within their organization, and investigate the root cause of errors with the goal of identifying ways to improve the medication-use system to prevent future errors and potential patient harm. The value of medication error reporting and other data gathering strategies is to provide the information that allows an organization to identify weaknesses in its medication-use system and to apply lessons learned to improve the system. The sheer number of error reports is less important than the quality of the information collected in the reports, the organization's analysis of the information, and its actions to improve the system to prevent harm to patients.

It is more important to create the open environment that encourages the reporting of errors and near errors than to develop less meaningful comparative error rates.

ISMP Launches Program to Track Vaccine Errors

ISMP has launched a National Vaccine Error Reporting Program (VERP) that allows health care providers to confidentially report vaccine administration errors and near misses. Health care providers from all practice settings, including pharmacies and physicians' offices, are encouraged to report all mistakes related to vaccines, regardless of whether any harm resulted from the incident. The program will help ISMP "better quantify the sources of errors and advocate for vaccine name, labeling, device, information, and other needed product changes to ensure patient safety," stated Michael Cohen, ISMP president. The ISMP VERP was designed with the assistance of the California Department of Public Health and with input from experts in the field, indicates ISMP. Reports sent to the ISMP VERP will be shared with FDA and forwarded to the vaccine manufacturer when applicable. ISMP also plans to work with the Centers for Disease Control and Prevention on information received to address vaccine-related safety. VERP can be accessed at *http://verp.ismp.org/.*

Providers Should Ensure Only Diluted Forms of Acetic Acid Are Used, ISMP Warns

ISMP has issued a National Alert Network (NAN) notice advising that health care organizations should take immediate steps to ensure that only diluted acetic acid solutions are used in patient care. ISMP advises that the use and purchase of glacial acetic acid, the most concentrated form of acetic acid available, should be eliminated. Several cases of severe burns, scarring, and other permanent damage to skin or mucous membranes due to the inadvertent application of glacial acetic acid have been reported to the National Medication Errors Reporting Program operated by ISMP. ISMP provides the following steps for preventing further such events:

- Remove glacial acetic acid, which has no use in its current form in clinical medicine, from the pharmacy and replace with vinegar (5% solution) or commercially available diluted acetic acid 0.25% (for irrigation) or 2% (for otic use).
- Restrict purchasing so that pharmacy staff is purchasing acetic acid for all procedural areas.
- Restrict choices for purchasing so that glacial acetic acid is not selected by mistake.
- Ensure the correct strength is ordered.
- Educate staff about the differences between glacial acetic acid and diluted forms of acetic acid.
- Order 5% as "vinegar," which reduces the potential for confusion with glacial acetic acid.
- Verify the product by requiring an independent double-check of acetic acid solutions before dispensing or applying the product.

Information on the cases reported and common reasons for the cases are included in the NAN alert, which is available on the ISMP Web site at *www.ismp.org/NAN/files/20130121.pdf.*

New FDA Training Video

FDA Drug Info Rounds, a series of online training videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better medication decisions. In the latest Drug Info Rounds video, pharmacists discuss how FDA Drug Safety Communications let health care providers, patients, and consumers know about newly observed potential risks of FDA-approved drugs. Drug Info Rounds videos are developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, and Division of Drug Information and are available on the FDA Web site at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.*

Progress Made in Implementing Recommendations Intended to Prevent Acetaminophen Overdose

Compelling progress has been made by stakeholders seeking to address the public health issue of acetaminophen overdose, indicates a white paper published by the National Council for Prescription Drug Programs (NCPDP). In 2011, NCPDP made recommendations that the health care industry take actions to support the safe use of acetaminophen, including recommending that pharmacies produce prescription labels with the complete spelling of acetaminophen and eliminating use of abbreviations such as "acet" or "APAP." Previous to that, in July 2010, the National Association of Boards of Pharmacy® (NABP®) recommended that "state boards of pharmacy prohibit the use of the abbreviation 'APAP' on prescription labels, and require that 'acetaminophen' be spelled out to assist in preventing the well-recognized danger of acetaminophen induced hepatotoxicity." The recommendation was based on established policy and a letter, sent by FDA to state boards of pharmacy, regarding the pharmacist's role in educating patients about acetaminophen induced hepatotoxicity caused by unintentional overdose. The recommendation was also consistent with the report of the NABP Task Force on Uniform Prescription Labeling Requirements, which made recommendations to encourage use of prescription labels that are organized in a patient-centered manner. NCPDP reports that pharmacy retailers "estimated to collectively represent more than half of the prescriptions dispensed in 2011, have either implemented or committed to a phased implementation" of the recommendation to use the complete spelling of acetaminophen on prescription labels. "This update to our white paper provides additional guidance for those industry stakeholders who have not yet implemented the new pharmacy labeling practices for acetaminophen-containing medicines," states Lee Ann Stember, president, NCPDP. The updated white paper is accompanied by a bulletin (PDF), available at *www.ncpdp.org/pdf/wp/NCPDPAcetaminophenInfoBulletin_PharmacyStakeholders.pdf,* developed for pharmacists that summarizes some of NCPDP's key recommendations regarding acetaminophen. In addition, the white paper, available for download at *www.ncpdp.org/ind_WP.aspx,* includes a list of resources for pharmacists to use in educating staff and pharmacy staff to use in educating patients (see Appendix D of the white paper). More information is available in an NCPDP news release available at *www.ncpdp.org/press/013113_NCPDP_Acetaminophen%20WP_FINAL.pdf.*

Pharmacists Rated High for Honesty and Ethical Standards in Gallup's 2012 Poll

Pharmacists ranked as the second most trusted profession in the 2012 Gallup Poll that asked consumers to rate 22 professions according to their honesty and ethical standards. Pharmacists were ranked as very high or high in this category by 75% of those surveyed, with nurses ranking first at 85%, and medical doctors third at 70%. Additional information on the results of the 2012 poll is available on the Gallup Web site at *www.gallup.com/poll/159035/congress-retains-low-honesty-rating.aspx*.

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Continued from page 1

Pharmacy Practice Act for operating without a permit pursuant to §40-43-83, resulting in discipline.

Board Welcomes New Inspector

Martin Chan joined the Board staff as an inspector on January 14, 2013. Mr Chan holds a doctor of pharmacy degree from Nova Southeastern University and a juris doctor degree from the University of New Hampshire. He has extensive experience in community pharmacy and as a diabetes coach for the Palmetto Pharmacist Network. He and his wife, Melissa, live in Travelers Rest, SC.

Reminder from DHEC Bureau of Drug Control

Per South Carolina Code of Regulations R 61-4, Section 145 (b), "The registrant shall notify the Bureau of Drug Control, DHEC [Department of Health and Environmental Control] of the loss or theft of any controlled substances upon discovery of such loss or theft. The registrant shall also complete DEA Form 106 regarding such loss or theft. . ."

Section 147 states, "Theft reports (DEA Form 106) as required by this regulation shall be filed with the Bureau of Drug Control not later than thirty days following the discovery of the theft. Failure to file theft reports within the thirty-day period shall result in the issuance of an order to show cause for revocation or suspension of registration under the Act."

Be aware that the requirement for reporting losses includes loss due to employee diversion, burglary, robbery, etc. Although Drug Enforcement Administration (DEA) 106 forms are available for online submission electronically, such notification is limited to DEA receipt. **South Carolina DHEC does *not* receive that electronic DEA submission. Registrants must print a copy of the online submission and send it by fax to 803/896-0656 or mail the hard copy to South Carolina DHEC – Bureau of Drug Control, 2600 Bull St, Columbia, SC 29201.**

Display of Permits, Licenses, and Registrations

§40-43-83(F) of the South Carolina Pharmacy Practice Act states, **"Permits issued under this section must be displayed in a conspicuous place in the permitted facility for which it was issued in such a manner that will enable an interested person to determine the name of the permittee, permit number, and permit expiration date."**

South Carolina Code of Regulations 99-15 states that a pharmacist **". . . shall display his annual renewal certificate in a conspicuous place in the primary pharmacy or permitted facility . . . in which he is employed, so that the annual renewable certificate is easily and readily observable by the public."**

§40-43-82(3) of the South Carolina Pharmacy Practice Act states, **". . . a pharmacy technician shall display his or her current registration in a conspicuous place in the primary pharmacy . . . so that the current registration is easily and readily observable by the public."**

The Board has reaffirmed its position that permits, renewal certificates for pharmacists, and renewal certificates for all pharmacy technicians must be displayed where the public can **see and read** all information on the permit or renewal certificates.

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 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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