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

Published to promote compliance of pharmacy and drug law

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LLR Notice

Department of Labor, Licensing, and Regulation's (LLR) Division of Professional and Occupational Licensing is currently going through a reorganization. LLR asks for and appreciates your patience and understanding as it makes this transition.

Please note: Effective May 1, 2011, LLR will no longer be able to accept cash. LLR encourages the use of its **online licensing services** to issue licenses as quickly as possible to its clients. Starting **May 15, 2011, a $25 service fee** will be instituted for licensing services done in person rather than online.

Pharmacy Technician Renewals

As required by law, pharmacy technicians will be renewing their licenses annually instead of biennially.

The 2011 renewal notices were mailed to pharmacy technicians on or about April 15. You will be mailed a renewal notice with a **user ID** and a **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 (PTCB)) to the South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy.**

If you choose not to renew online, you can request a renewal form from the Board and renew by mailing the completed form and proper fees to the Board office. **Applications need to be received in the Board office by June 1, 2011. Pharmacy technicians who do not renew prior to June 30, 2011, will be assessed penalties and shall not work as pharmacy technicians until a 2011-2012 registration is in hand or disciplinary action may result.** If you do not renew online, please document the date the application is mailed. **The Board of Pharmacy recommends the paper renewal be sent 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 continuing education (CE) (four hours must be live) per year with a total of 20 hours (eight hours must be live). The CE for the current renewal is for the years 2009-2011. **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 is dated after your renewal is received in the Board office.

Facility Permit Renewals

Facilities are again required to renew their permits on an annual basis, as required by law. You are no longer allowed to renew your license biennially.

The permit renewal notices and forms were mailed out mid-April 2011 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 South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy 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 request a renewal form from the Board or print 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, 2011, or a $50 late fee will be assessed. After June 30, 2011, 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 practice act for operating without a permit pursuant to §40-43-83, resulting in discipline.

DHEC Bureau of Drug Control – Schedule II Prescription Changes

By Wilbur L. Harling, RPh, Director, South Carolina Department of Health and Environmental Control (DHEC) – Bureau of Drug Control

Question: What changes may a pharmacist make to a prescription written for a controlled substance in Schedule II?

Answer: On November 19, 2007, Drug Enforcement Administration (DEA) published in the *Federal Register* (FR) the Final Rule entitled Issuance of Multiple Prescriptions for Schedule II Controlled Substances (72 FR 64921). In the preamble to that rule, DEA stated that "the essential elements of the [schedule II] prescription written by the practitioner (such as the name of the controlled substance, strength, dosage form, and quantity prescribed) . . . may not be modified orally."

The instructions contained in the rule's preamble are in opposition to DEA's previous policy, which permitted the same changes a pharmacist may make to Schedules III through V controlled

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Obtain Your NABP e-Profile ID Online Now, ID Required for ACPE-Accredited CPE

The new National Association of Boards of Pharmacy® (NABP®) CPE Monitor service, a collaborative effort between NABP, the Accreditation Council for Pharmacy Education (ACPE), and their providers, will allow pharmacists and technicians to easily track their ACPE-accredited continuing pharmacy education (CPE) credits beginning in the latter part of 2011. In addition, the service will provide a streamlined reporting and compliance verification process for participating state boards of pharmacy. When pharmacists and technicians complete an ACPE-accredited CPE program, their participation data will be sent electronically from the provider to ACPE, then to NABP for recording into the matching NABP e-Profile. Then, if the board of pharmacy participates in CPE Monitor, the pharmacists' or technicians' CPE credits will be automatically transmitted to the board, saving pharmacists and technicians the trouble and expense of documenting and submitting compliance with state-mandated CPE requirements for license renewal. This eliminates paper forms and the overall need to submit paper copies of CPE statements of credit to the board of pharmacy for CPE activities from ACPE-accredited providers.

For convenience, the NABP e-Profile will be available 24/7 for viewing a comprehensive list of the CPE activities completed. All information will be maintained in a highly secure environment. NABP does not distribute any personal information for commercial purposes without consent.

To prepare for the new process, pharmacists and technicians are encouraged to obtain their NABP e-Profile identification to ensure their e-Profile is properly set up. Beginning in the latter part of 2011, all pharmacists and technicians will be able to provide their NABP e-Profile ID, plus their birth date (mmdd) to receive credit for any accredited CPE activities from ACPE-accredited providers. Providers will ask CPE participants to provide the ID either when registering or when submitting participation data to the provider. Please note that CPE Monitor will not initially track CPE from non-ACPE-accredited providers. This feature will be added in Phase 2 of the CPE Monitor service, and, until then, pharmacists and technicians will need to submit non-ACPE-accredited CPE directly to their board of pharmacy when required to do so.

NABP and ACPE will work with CPE providers to ensure an adequate amount of time is allotted to implement this new service.

Pharmacists can obtain their ID by creating an NABP e-Profile using the portal in the Pharmacists section of the NABP Web site at *www.nabp.net/pharmacists*. Technicians can obtain their ID by creating an NABP e-Profile using the portal in the Technicians section of the NABP Web site at *www.nabp.net/technicians*. Visit *www.MyCPEmonitor.net* for more information.

FDA Asks Manufacturers to Limit Acetaminophen Strength

In the interest of patient safety, Food and Drug Administration (FDA) asked drug manufacturers to limit the strength of acetaminophen in prescription drug products – which are predominantly combinations of acetaminophen and opioids – to 325 mg per tablet, capsule, or other dosage unit. In addition, FDA reports that the labels of all prescription drug products that contain acetaminophen will now include a boxed warning that highlights the potential for severe liver injury and a warning that highlights the potential for allergic reactions. FDA has taken these actions to reduce the risk of severe liver injury and allergic reactions associated with acetaminophen. FDA notes that over-the-counter products containing acetaminophen are not affected by this action.

While the maximum amount of acetaminophen in a prescription tablet, capsule, or other dosage unit will be limited to 325 mg, the total number of tablets or capsules that may be prescribed and the time intervals at which they may be prescribed will not change as a result of the lower amount of acetaminophen. Additional information for health care providers and patients is included in an FDA Drug Safety Communication available on the FDA Web site at *www.fda.gov/Drugs/DrugSafety/ucm239821.htm.*

Looking for Risk

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 a 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.*

Health care organizations focused on improving patient safety must first identify, ascertain the causes of, and employ strategies to reduce risk. Everyone on staff in an organization has responsibility for risk assessment and, therefore, risk management.

This includes involving patients in their care and seeking their help to identify risk in the system. Assessing risk in an organization is important to understanding and prioritizing areas of highest risk and for discovering which improvements will have the greatest overall impact on patient safety.

FMEA

The Failure Mode and Effects Analysis (FMEA) process is a "systematic method of identifying and preventing product and process problems before they occur." FMEA is the tool that has the potential to be an integral part of any risk assessment and, therefore, the risk management process.

FMEAs focus on identifying and removing defects, enhancing safety, and increasing customer satisfaction.

AROC

Assessing Risk and Opportunities for Change (AROC) is designed to help community pharmacy personnel identify potential medication safety risks and prevent errors. Pharmacists can use these materials and tools to pinpoint specific areas of weakness in their medication delivery systems and to provide a starting point for successful organizational improvements.

Pharmacists' Role

Pharmacists are often assumed to be the "guardians" in ensuring that medication errors do not occur. This expectation is unrealistic, because avoiding error is a health care team effort. It has, however been suggested that pharmacists should assume a leadership role in implementing safe medication use efforts in their organization.

Objectives for the pharmacist and other pharmacy staff who participate in the assessment process:

- Explain the important processes and sub-processes of medication use from prescription through administration.
- Participate in identifying failure modes and risk throughout the entire medication process, especially in information that should be available to the prescriber and nurse, as well as describing the steps in the process that occur after the medication order is transferred to the pharmacy.
- Offer possible causes for medication errors because of breakdowns in the prescription to administration process.
- Identify effects, as well as their severity and probability, when a system failure occurs.
- Offer suggestions, along with all team members, for actions that should be taken to prevent medication errors.

Pharmacists are an integral part of any medication safety assessment process. They not only offer information – as do the other disciplines in the organization – they can also expand their knowledge through participating in these risk assessments. Pharmacy participation should include frontline staff, pharmacists, pharmacy technicians, and pharmacy support staff. It is important to have multilevel involvement so that all system enhancements are discussed and identified.

To learn more about assessing risk in acute care pharmacy visit *www.ismp.org/Tools/pathways.asp.*

To learn more about assessing risk in community pharmacy visit *www.ismp.org/communityRx/aroc/*.

NABP Launches New and Improved NAPLEX/ MPJE Application in March

In March 2011, NABP launched a new and improved application process for the North American Pharmacist Licensure Examination® (NAPLEX®) and the Multistate Pharmacy Jurisprudence Examination® (MPJE®). The online application was upgraded to be more user friendly, allowing candidates to perform more registration tasks and providing status information to examination candidates.

In addition to providing the basic features of registering for the NAPLEX, NAPLEX score transfer, and MPJE, the new application also allows candidates to make changes to, add to, or withdraw an application, eliminating the need for candidates to call NABP for this service. Changes that can be made to an application include registering for the MPJE in additional jurisdictions and adding NAPLEX score transfer requests until the time of the examination. Technological enhancements to the application allow for the elimination of the previous requirement that candidates submit score transfer requests five business days prior to sitting for the NAPLEX.

The new application also gives candidates who miss sitting for an examination or who do not cancel within two business days of their appointment the ability to submit resitting fees online rather than having to send a payment to NABP via mail. This expedites the receipt of the candidate's new Authorization to Test so that he or she may schedule another examination appointment more quickly.

An additional benefit to candidates is the ability to monitor the status of their profile. After submitting an application, candidates can log in to their profile and see if the application has been received; if eligibility has been requested, granted, denied, or expired; if Authorization to Test has been generated; if the application has been withdrawn or expired; and history of examinations taken.

The profiles of candidates who registered for the NAPLEX or MPJE before the new application was launched will need to create a user name and password through the new application so that they can view the historical data of their NAPLEX and MPJE registrations. Upon creating a new user account, the system will match the newly created account with applications previously submitted or currently in progress so that all the information will be viewable by the candidate.

The new application also allows users to update their profiles as needed and review past orders.

In addition, the score results for the NAPLEX and MPJE are also accessible when candidates log in to the application, provided that the board for which the candidate tested participates in the online score interface. Currently, 25 boards utilize this service.

Overall, candidates can expect a clearer and smoother registration process because both front and back-end functionality of the application has been streamlined and tightly integrated.

New FDA Drug Info Rounds 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 the role of FDA in responding to and mitigating drug shortages. Drug Info Rounds is developed with contributions from pharmacists in the FDA's Center for Drug Evaluation and Research, Office of Communications, and Division of Drug Information. FDA Drug Info Rounds training videos may be accessed on the FDA Web site at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.*

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substance prescriptions after oral consultation with the prescriber. DEA recognizes the resultant confusion regarding this conflict and plans to resolve this matter through a future rulemaking. **Until that time, pharmacists are instructed to adhere to state regulations or policy regarding** those changes that a pharmacist may make to a Schedule II prescription after oral consultation with the prescriber.

This is the DEA policy on Schedule II changes, which may be found on the DEA Web site, *www.deadiversion.usdoj.gov,* under General Questions and Answers.

Below is the South Carolina policy on Schedule II changes:

a. After oral consultation with the prescribing practitioner, pharmacist is permitted to change the patient's address, drug strength, drug quantity, dosage form, and directions for use.

b. The pharmacist **is not permitted to make changes** to the patient's name, controlled substance prescribed (except for generic substitution), prescriber's signature, or issue date.

If you have any questions, contact Wilbur Harling at 803/896-0636.

CPE Monitor Service Launched

The National Association of Boards of Pharmacy®, in collaboration with the Accreditation Council for Pharmacy Education (ACPE) is launching a continuing pharmacy education (CPE) monitoring service. All pharmacists and technicians should review the article in the National Pharmacy Compliance News section of this *Newsletter.* This version of the CPE Monitor Service will only track ACPE-accredited CPE, but inclusion of continuing medical education, Category I, monitoring is being explored for Phase II.

Federally Qualified Health Clinics

The South Carolina Code of Laws has been amended to add Act 194, **§40-43-70** to the Practice Act. Any pharmacist involved with a Federally Qualified Health Clinic (FQHC) should review this section of law on the Board of Pharmacy Web site. A new FQHC Drug Outlet Permit has been added to accommodate the requirements of this law for clinics that do not have a pharmacy on site.

Compliance Tips

§40-43-82(C) Notwithstanding any other provision of this chapter, a supervising pharmacist may authorize a **certified pharmacy technician** to:

(1) receive and initiate verbal telephone orders;

(2) conduct one time prescription transfers;

Upon routine inspections it has been determined that technicians who **are not "state-certified technicians"** are initiating and receiving verbal orders and conducting one-time prescription transfers. These violations may result in fines to the technicians, pharmacists on duty, and the pharmacist-in-charge.

A verbal order for a prescription may only be initiated or received by a pharmacist, pharmacy intern or extern authorized by supervising pharmacist, or a state-certified pharmacy technician authorized by a supervising pharmacist.

As a reminder, a technician can be PTCB certified, but has not met all the requirements in **Section 40-43-82(B)** to become **state certified.**

Relief pharmacists need to be aware of the technicians' credentials working their shifts by checking their registration to determine which technicians' registration certificates are for a "Pharmacy Technician" (registered) or "State-Certified Pharmacy Technician" (state). This practice would ensure compliance with the technician ratio and expanded roles.

§40-43-86(B)(3) The pharmacist-in-charge shall have the following responsibilities:

(d) **responding** to the Board of Pharmacy regarding any **violations** brought to the pharmacist-in-charge's attention.

Please note the following statement on the inspection form: "This inspection report describes alleged violations of the Pharmacy Act . . . **You must notify the Board in writing of those corrections within ____ days."**

There appears to be an increase in the number of pharmacists-in-charge that are not sending in their responses in the designated number of days to the inspector, which may result in disciplinary action from the Board. The response may either be by e-mail or by fax **to the attention of the inspector** at 803/896-4596. A list of the inspectors and their e-mail addresses is on the Web site under the Staff tab.

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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