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

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2015 Pharmacist Renewal Notices Are on the Way!

The 2015 renewal notices will be mailed to you in late February. The South Carolina Department of Labor, Licensing, & Regulation – Board of Pharmacy has enhanced its online renewal system to make it easier and more convenient for you to renew your license. You will receive a renewal notice with a **user ID** and a **password** that will allow you to access the online renewal website. If you choose not to renew online, you can request a paper renewal form from the Board office and renew by mailing the completed form and proper fees to that office. Applications for renewal must be filed no later than March 31, 2015, to avoid a penalty. If you do not renew online, please document the date the application is mailed. The Board recommends the paper renewal be sent via **certified mail with a return receipt requested.** Postage machines do not provide acceptable proof of mailing.

Applications submitted for renewal between April 1 and April 30, 2015, must include a penalty fee of $50 for late renewal in addition to evidence that the applicant meets the renewal requirements and has paid the appropriate fees. If you do not renew your license by April 30, 2015, it will be considered lapsed. You can be disciplined for unlicensed practice if you continue to work in South Carolina after that date.

Pharmacist CE Requirements for Renewals

To renew online, you must indicate you have completed the required 15 hours of continuing education (CE). Six of those hours must be live and 50% of the total must be in drug therapy or patient management. **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 you completed the CE requirements or if the required CE is dated **after** your renewal is received in the Board office.

Board Welcomes New Inspector

Bonnie Wilgus joined the Board staff as a pharmacist inspector on November 3, 2014. She graduated with a bachelor of science degree in pharmacy from the Medical University of South Carolina in 1990. Bonnie has practiced for 25 years in retail, clinical, and long-term care pharmacy practice settings. She lives in Charleston, SC, with her son, Parker, and her son, John, is a sophomore at Winthrop University. The Board and staff are happy to welcome her.

New Director Named for DHEC Bureau of Drug Control

The South Carolina Department of Health and Environmental Control (DHEC), Bureau of Drug Control named Lisa Thomson, RPh, as director, effective August 2, 2014. Thomson has worked for the Bureau of Drug Control since 2002 as an inspector and district director. She has retail and hospital pharmacy experience. She also worked in research and development for National Data Corporation's healthcare division. She graduated from the Medical University of South Carolina in 1987 with a bachelor of science degree in pharmacy.

Thomson sincerely encourages open dialogue with pharmacists, pharmacy technicians, interns, and practitioners related to the controlled substance statutes and regulations in an effort to avoid potential confusion, misunderstanding, or violations. All of the Bureau of Drug Control staff welcome the opportunity to provide education and assistance with compliance. The Board and staff look forward to working with Thomson in her new role.

CE Requirements for Pharmacy Technicians and State Certified Pharmacy Technicians

- Ten hours of Accreditation Council for Pharmacy Education (ACPE) or continuing medical education (CME) Category I CE are required each registration year for renewal. Of the 10 hours, a minimum of four hours must be "live" hours. CE must be taken **before** renewing a registration each year.
- **There are no exemptions to the CE requirement for technicians.**
- Technicians may take CE that is designated for pharmacists (P) or technicians (T).
- To determine if a CE is live (L), home (H), or combination (C), use the ACPE universal program number (UPN). 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.

Continued on page 4

DEA Finalizes Rule on CS Prescription Drug Disposal

In September 2014, Drug Enforcement Administration (DEA) published its final rule, titled the Disposal of Controlled Substances, that allows some DEA registrants to modify their registration to become authorized collectors. Under the new rule, some DEA registrants, including retail pharmacies, hospitals/clinics with an on-site pharmacy, manufacturers, distributors, reverse distributors, and narcotic treatment programs, may modify their registration with DEA to become authorized collectors. The final rule implements the Secure and Responsible Drug Disposal Act of 2010, which authorized DEA to develop and implement regulations that would allow authorized entities other than law enforcement to collect unused and unwanted prescription drugs, including controlled substances (CS), for disposal purposes. Proper disposal of unused prescription medication is a key method of preventing and reducing prescription drug abuse. The final rule took effect on October 9, 2014.

The full rule is available on the *Federal Register* website at *www.federalregister.gov/articles/2014/09/09/2014-20926/disposal-of-controlled-substances.*

System-Based Causes of Vaccine Errors

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization 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 provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

Immunizations are widely recognized as one of the most successful and cost-effective health interventions ever introduced worldwide. However, errors with vaccines can result in an unintended and unrecognized source of vulnerability. While the immediate impact of a vaccine-related error on a patient may not be serious, such errors may render the vaccine ineffective or reduce its effectiveness, leaving patients unprotected against serious diseases such as hepatitis A, hepatitis B, diphtheria, tetanus, measles, cervical cancer, and many others. In September 2012, ISMP (in cooperation with the California Department of Public Health) established the ISMP National Vaccine Errors Reporting Program (VERP) to collect data about the type of vaccine errors occurring and the reasons they occur. In ISMP's November 28, 2013 newsletter *(www.ismp.org/sc?id=307),* ISMP provided a summary analysis of error reports submitted to the ISMP VERP during its first year. The vaccinations that are most frequently associated with errors included *Haemophilus influenzae* type b conjugate (Hib); diphtheria and tetanus toxoids, acellular pertussis adsorbed, and inactivated poliovirus (DTaP-IPV); tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis adsorbed (Tdap); diphtheria, tetanus toxoid, and acellular pertussis adsorbed (DTaP); hepatitis A (HepA); hepatitis B (HepB); human papillomavirus quadrivalent (types 6, 11, 16, and 18), recombinant (HPV4); zoster; and measles, mumps, rubella, and varicella (MMRV). The most common contributing factors associated with the reported vaccine errors included mistakes in choosing age-dependent formulations of vaccines intended to prevent the same diseases; unfamiliarity with the vaccine, particularly its dose, dosing schedule, age specifications, route of administration, and the vaccine's various components (eg, combination vaccines, diluents, and powder); failure to check or verify the patient's age, health record, or state registry; similar vaccine names and abbreviations; similar and confusing vaccine labeling and packaging; unsafe storage conditions (eg, stored near other similar vaccines or unwanted temperature fluctuations); and expiration dates not noticed or misunderstood.

Practice Recommendations. Involve the patient or parent(s)/caregiver(s) in a vaccine verification process by:

1) Documenting the vaccine name, formulation (pediatric or adult, if applicable), lot number, and expiration date on the patient's vaccine record **prior** to preparation/administration of the vaccine,
2) Bringing the vial and syringe or the prefilled syringe along with the immunization record into the exam room,
3) Asking the patient or parent/caregiver to simultaneously verify the information on the immunization record while a health care provider reads the information on the label aloud,
4) Asking the patient or parent/caregiver if the verified vaccine is what he or she expected to be administered (based on an immunization schedule provided to the patient or parent/caregiver previously),
5) Preparing and administering the vaccine immediately after verification, and
6) Documenting the vaccine on the patient's medical record.

FDA Warns of Growing Network of Rogue Wholesale Drug Distributors

Through a new educational program called Know Your Source, Food and Drug Administration (FDA) is warning pharmacists and other health care providers to watch for counterfeit and unapproved drugs. Aimed at protecting patients from unsafe and ineffective drugs, the program advises providers to only purchase drugs from wholesale drug distributors licensed in their state. Further, FDA offers tips to providers to protect patients, including being wary of offers too good to be true, and ensuring that all drugs received are FDA-approved medications.

Another way that pharmacies can be assured of the legitimacy of a wholesale distributor is to look for the National Association of Boards of Pharmacy® (NABP®) Verified-Accredited Wholesale Distributors® (VAWD®) Seal. Those wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws, as well as NABP's VAWD criteria. Wholesale distributors that display the VAWD Seal as part of their accreditation have undergone a criteria compliance review, including a rigorous

review of their operating policies and procedures, licensure verification, survey of facility and operations, background checks, and screening through the NABP Clearinghouse. Accredited facilities are reviewed annually and undergo a site survey every three years. Created in 2004, the accreditation program plays a pivotal role in preventing counterfeit drugs from entering the United States drug supply.

Additional information about the VAWD program is available in the Programs section of the NABP website. Know Your Source is available at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm389121.htm*.

PTCB Implements Changes to CE Requirements

In 2015, the Pharmacy Technician Certification Board (PTCB) will implement two changes in recertification requirements for certified pharmacy technicians (CPhTs) in accordance with its certification program changes announced in 2013. First, any continuing education (CE) hours earned by a CPhT will need to be pharmacy technician-specific in order to qualify toward recertification. Second, PTCB will reduce the number of allowable "in-service" CE hours from 10 to five. PTCB's certification program changes are intended to support and advance improved patient care and safety throughout pharmacy practice, a PTCB press release indicates. The changes are the result of a PTCB initiative that began with a 2011 summit on future directions for pharmacy technicians.

Additional information can be accessed on the PTCB website at *www.ptcb.org*.

Security Guidelines Available as Rate of Pharmacy Robberies Still a Concern

Nationally, pharmacy robberies dipped slightly from 745 in 2012, to 713 in 2013, according to a report compiled by *Drug Topics* using DEA statistics. The 10 states that had the most robberies are in stark contrast to other states that had no robberies (South Dakota, North Dakota, and Alaska) or as few as one or two (such as Montana and Illinois), reports *Drug Topics*. However, fueled by the prescription drug abuse epidemic, pharmacy robberies still pose a threat to the safety of personnel and customers. The report lists the top 10 states that had the most pharmacy thefts in 2013. Arizona experienced the most pharmacy robberies in 2013 with 77 incidents, and Indiana took second place with 71 robberies. The report, titled "Top 10 states for pharmacy robberies," may be found at *http://drugtopics.modernmedicine.com/drug-topics/content/tags/arizona/top-10-states-pharmacy-robberies?page=full.*

NABP partnered with DEA to create an educational pamphlet identifying key strategies pharmacists can take to secure their stores against robberies, which can be downloaded at *www.deadiversion.usdoj.gov/pubs/brochures/pharmtheft.pdf*. In addition, some boards of pharmacy have identified best practices for preventing pharmacy theft, and have supported these practices through regulations or recommendations for their licensees. For example, the New Jersey State Board of Pharmacy's *Pharmacy Security Best Practices* document recommends that all Schedule II and III CS be stored in a "safe or substantially constructed steel cabinet that is locked at all times," with only licensed pharmacists having access. Additional recommendations include annual pharmacist-in-charge self-assessments and interfacing with prescribers and customers, among others. The best practices document can be downloaded from the New Jersey Consumer Affairs website at *www.njconsumeraffairs.gov/press/05012013.pdf.*

Private organizations have also developed resources to assist pharmacies in improving security. One such resource is the RxPATROL program, which works with law enforcement, the pharmacy community, and security professionals to maintain a database containing detailed information about pharmacy robberies and other losses. In addition, the RxPATROL website, *www.rxpatrol.com*, provides training videos and a pharmacy security checklist.

Further, NABP members directed the Association to convene a task force to review strategies that states have taken to prevent theft and drug diversion. The Task Force to Examine Strategies for Preventing and Reacting to Pharmacy Robberies and Thefts met on October 22-23, 2014, to discuss these issues.

Assured Brand Naproxen Tablets Recalled Due to Packaging Error

In October 2014, Contract Packaging Resources of Greensboro, NC, a drug repackaging company, issued a voluntary recall of nearly 12,000 boxes of Assured brand naproxen sodium tablets because some cartons contain bottles of 200 mg ibuprofen softgels instead, a press release posted to the FDA website indicates. The packaging error affected boxes of Assured brand naproxen sodium tablets 220 mg, 15 count (Lot Number FH4102A), which were distributed to and sold at Dollar Tree stores and on the Dollar Tree website. Contract Packaging Resources is contacting customers to arrange for replacement of all recalled products. Adverse reactions or quality problems experienced with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting Program.

More information is available on the FDA website at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm419769.htm.*

Martin Avenue Pharmacy Issues Voluntary Recall for All Sterile Compounded Preparations

Martin Avenue Pharmacy, Inc, of Naperville, IL, issued a voluntary recall for all in-date compounded sterile preparations due to a lack of sterility assurance in August 2014. Following a recent FDA inspection that revealed "quality control procedures that present a risk to sterility assurance," the company issued the recall out of an abundance of caution, indicates a news release posted to the FDA website. Martin Avenue Pharmacy supplied compounded sterile preparations to offices of licensed medical professionals and individuals in multiple states including Illinois, Wisconsin, Ohio, Michigan, Florida, Alabama, and Texas until August 20, 2014. A full list of recalled products is available on the Martin Avenue Pharmacy website (registration required). FDA urges consumers and health care providers to report adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information Adverse Event Reporting Program.

More information is available on the FDA website at *www.fda.gov/Safety/Recalls/ucm412431.htm*.

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Continued from page 1

Please note that college health-related fields are not acceptable in lieu of the required CE hours. The Board strongly encourages technicians to obtain technician-specific CE programs. Please share this important information with your pharmacy technicians and state certified pharmacy technicians.

Common Violations on Pharmacy Inspections

- Expired drugs and unlabeled drugs in active stock. §40-43-86(A)(16)(c)
- Out of range refrigerator/freezer temperatures. §40-43-86(A)(16)(d)
- Consultant pharmacist performs written monthly inspections. §40-43-86(C)(1)(f)
- Education and training in the art and science of compounding. §40-43-86(CC)(3)
- All supplies and equipment required for administration of influenza vaccine per state protocol must be in stock. Refer to Appendix B of the protocol. §40-43-190
- Incomplete compounding logs and formulas. §40-43-86(CC)(6)
- Required documentation on prescription transfers. §40-43-86(G)
- Policy and procedure for management of recalls. §40-43-86(B)(5)

Board Meeting Calendar

The Board welcomes all interested individuals to attend Board and committee meetings held throughout the year at the Board office in Columbia, SC. Board meeting dates are listed below.

- March 18, 2015
- June 17-18, 2015
- September 16-17, 2015
- November 18, 2015

The Board also has many special committees that meet periodically throughout the year to address specific concerns for the pharmacy community. Committee meeting dates are listed below.

- Legislative, Compounding, and Medication Integrity committees
  - ◊ February 13, 2015
  - ◊ April 10, 2015
  - ◊ May 8, 2015
  - ◊ July 10, 2015
  - ◊ October 9, 2015
- Pharmacy Practice and Technology, Nuclear, and Pharmacy Technician committees
  - ◊ February 26, 2015
  - ◊ April 23, 2015
  - ◊ May 28, 2015
  - ◊ July 23, 2015
  - ◊ October 22, 2015
- Non-Resident Application Review committee
  - ◊ February 10, 2015
  - ◊ February 19, 2015
  - ◊ April 7, 2015
  - ◊ April 15, 2015

These meetings are held at the discretion of the committee chairperson.

- Compounding – Carole Russell, RPh, Chairperson
- Legislative – Addison Livingston, PharmD, RPh, Chairperson
- Pharmacy Practice and Technology – Rob Hubbard, RPh, Chairperson
- Scope of Practice – Rob Hubbard, RPh, Chairperson
- Pharmacy Technician – Rebecca Gillespie, PharmD, RPh, Chairperson
- Medication Integrity – David Banks, RPh, Chairperson
- Nuclear – Spencer Morris, PharmD, RPh, Chairperson
- Recovering Professionals Program – Leo Richardson, PhD
- Non-Resident Application Review – Addison Livingston, PharmD, RPh, Chairperson

For more information, you may check the Board's website, or if you would like to be added to the agenda distribution list for Board or committee meetings, please contact the Board office.

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™ (NABPF™) 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 NABPF or the Board unless expressly so stated.

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