May 2018

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

Published to promote compliance of pharmacy and drug law

Kingstree Bldg, 110 Centerview Dr • PO Box 11927 • Columbia, SC 29211-1927
www.llr.state.sc.us/pol/pharmacy • 803/896-4700

Pharmacy Technician Renewals

The 2018 renewal notices were mailed to pharmacy technicians in early April. You were mailed a renewal notice with a **user ID,** and you will be required to reset your **password** due to security changes to access the online renewal website. A current email address is required to renew online. **New this year,** pharmacy technicians are exempt from continuing pharmacy education (CPE) requirements for the first renewal period following initial registration.

To Add an Email Address

- Visit *www.llr.state.sc.us/pol/pharmacy.*
- On the right-hand side of the page, under Contact Us, click on Contact.Pharmacy@llr.sc.gov.
- In the subject line, enter "email address update."
- Provide your name, technician registration number, and the email address you want to use.

To Reset Your Password

- Visit *https://eservice.llr.sc.gov/SSO/Login/RecoverPass.*
- Enter your user ID.
- Check the "I'm not a Robot" box and click the "Retrieve" box.
- A link to reset your password will be emailed to you.

NABP e-Profile ID

You **must** have a National Association of Boards of Pharmacy® (NABP®) e-Profile ID for CPE Monitor® to renew online. CPE Monitor is a service used to document and report your CPE credits. You will be asked to provide the e-Profile ID number on the renewal form, and you cannot renew online without one.

To create an e-Profile ID, visit *www.nabp.pharmacy.* Click on **"NABP e-Profile Login"** at the top of the page, then select the **"Customers"** tile and create a login. For common questions about creating an e-Profile or internet browser requirements, click on the e-Profile FAQs link at the bottom of the NABP website.

If you are a state-certified pharmacy technician and your national certificate (from the Pharmacy Technician Certification Board) has expired, you must mail a copy of your current national certificate 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 need to be received in the Board office by June 1, 2018. Pharmacy technicians who do not renew prior to June 30, 2018, will be assessed penalties and cannot work as pharmacy technicians until a 2018-2019 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 recommends the paper renewal be sent via certified mail with a return receipt requested.**

Facility Permit Renewals

The permit renewal notices and forms were mailed out in mid-April 2018 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 you will be required to reset your **password** due to security changes to access the online renewal website. If you do not have an email address or know your password, please refer to the previous article on how to add an email address or reset your password.

If you choose not to renew your permit online, you may download a renewal form from the Board's website. 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, 2018, or a $50 late fee will be assessed. After June 30, 2018, 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 (PIC), 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 South Carolina Code Annotated §40-43-83, resulting in discipline.

Board Approves Expungement Policy

At the March 14, 2018 Board meeting, the Board approved the following Expungement Policy. Pursuant to S.C. Code Ann. §40-1-120(E), the Board hereby establishes the following procedure to allow a licensee/permittee who has been issued a reprimand to petition the Board for expungement of the reprimand from the licensee/permittee's record.

Continued on page 4

National Pharmacy Compliance News

May 2018

NABPF
National Association of Boards of Pharmacy Foundation

The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

FDA Requires Labeling Update on Opioid-Containing Cough and Cold Medicines

In January 2018, Food and Drug Administration (FDA) announced that the agency is requiring safety labeling changes to limit the use of prescription opioid cough and cold medicines containing codeine or hydrocodone in children younger than 18 years old because the serious risks of these medicines outweigh their potential benefits in this population. After safety labeling changes are made, these products will no longer be indicated for use to treat cough in any pediatric population and will be labeled for use only in adults aged 18 years and older. In addition, labeling for the medications will be updated with additional safety information for adult use. This update will include an expanded Boxed Warning notifying consumers about the risks of misuse, abuse, addiction, overdose and death, and slowed or difficult breathing that can result from exposure to codeine or hydrocodone. Additional information is available in FDA's news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm592109.htm.*

Latest NDTA Shows Opioids Pose Significant Impact to Public Health

Drug Enforcement Administration (DEA) indicates a significant shift in the overall drug threat reported by law enforcement over the last 10 years with opioids (including controlled prescription drugs, fentanyl and other synthetic opioids, and heroin) reaching epidemic levels and impacting significant portions of the United States. According to the *2017 National Drug Threat Assessment (NDTA)* report, every year since 2001, controlled prescription drugs, specifically opioid analgesics, have been linked to the largest number of overdose deaths of any illicit drug class, outpacing those for cocaine and heroin combined.

From 2007 to 2010, responses to the National Drug Threat Survey indicate cocaine was the greatest national drug threat, followed by a significant decline as the heroin threat increased between 2010 and 2016, eventually becoming the greatest national drug threat in 2015.

Illicit fentanyl and other synthetic opioids, primarily sourced from China and Mexico and shipped directly to the US or trafficked overland via Mexico and Canada, are contributing factors in the current synthetic opioid overdose epidemic. Traffickers in the US usually mix fentanyl into heroin products and sometimes other illicit drugs or press it into counterfeit prescription pills, often without users' awareness, which leads to overdose incidents, notes the *2017 NDTA.* To access the *2017 NDTA,* visit *www.dea.gov/divisions/hq/2017/hq102317.shtml.*

FDA Recognizes Eight European Drug Regulatory Authorities Capable of Conducting Inspections

FDA has determined it will recognize eight European drug regulatory authorities as capable of conducting inspections of manufacturing facilities that meet FDA requirements. The eight regulatory authorities found to be capable are those located in Austria, Croatia, France, Italy, Malta, Spain, Sweden, and the United Kingdom. This achievement marks an important milestone to successful implementation and operationalization of the amended Pharmaceutical Annex to the 1998 US-European Union (EU) Mutual Recognition Agreement, which enables US and EU regulators to utilize each other's good manufacturing practice inspections of pharmaceutical manufacturing facilities. "By partnering with these countries, we can create greater efficiencies and better fulfill our public health goals, relying on the expertise of our colleagues and refocusing our resources on inspections in higher risk countries," said FDA Commissioner Scott Gottlieb, MD, in a news release located at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm583057.htm.*

Incorrect Use of Insulin Pens at Home Can Cause Severe Hyperglycemia

The National Coordinating Council for Medication Error Reporting and Prevention has issued an alert on the incorrect use of insulin pens at home causing severe hyperglycemia in patients, including one reported fatality. The Institute for Safe Medication Practices National Medication Errors Reporting Program has received several reports of patients who failed to remove the inner cover of standard insulin pen needles prior to administering insulin. In the latest such event, a patient with type 1 diabetes did not know to remove the standard needle cover and was unaware she was using the pen incorrectly and had not been receiving any of the insulin doses; the patient developed diabetic ketoacidosis as a result and died.

Since insulin pens may differ between pens with automatic needle retraction devices and those with standard needle covers that require manual removal before administering insulin, it is imperative that removal of

needle covers be explained to patients who are issued standard insulin pens during their diabetes education. Pharmacists should verify that a patient understands the appropriate administration technique whenever pens and insulin needles are dispensed, notes the alert, which can be viewed at *www.nccmerp.org/sites/default/files/nan-20171012.pdf.*

FDA Advises on Opioid Addiction Medications and Benzodiazepines

Opioid addiction medications – buprenorphine and methadone – should not be withheld from patients taking benzodiazepines or other drugs that depress the central nervous system (CNS), advises FDA. The combined use of these drugs increases the risk of serious side effects; however, the harm caused by untreated opioid addiction usually outweighs these risks. Careful medication management by health care providers can reduce these risks, notes a safety alert. FDA is requiring this information to be added to the buprenorphine and methadone drug labels along with detailed recommendations for minimizing the use of medication-assisted treatment drugs and benzodiazepines together.

Health care providers should take several actions and precautions and should develop a treatment plan when buprenorphine or methadone is used in combination with benzodiazepines or other CNS depressants. Additional information may be found at *www.fda.gov/Drugs/DrugSafety/ucm575307.htm.*

Only About 3% of Pharmacies and Other Entities Voluntarily Maintain a Prescription Drug Disposal Bin, GAO Reports

In response to the US Senate Judiciary Committee's request to review DEA's requirements for authorized collectors of prescription drugs and participation rates, the US Government Accountability Office (GAO) found that only about 3% of pharmacies and other entities eligible to collect unused prescription drugs for disposal have volunteered to do so. As of April 2017, 2,233 of the 89,550 eligible entities had registered with DEA to use disposal bins to collect unused prescription drugs. The majority of the authorized collectors were pharmacies, followed by hospitals or clinics. Factors that affected voluntary participation in maintaining disposal bins for the public included cost, uncertainty of proper implementation, and participation in other drug disposal efforts.

GAO found that participation rates varied by state. Connecticut, Missouri, and Maine had the lowest participation rates as of April 2017. North Dakota had the highest participation rate, followed by Alaska. The report, *Preventing Drug Abuse: Low Participation by Pharmacies and Other Entities as Voluntary Collectors of Unused Prescription Drugs,* is located on the GAO website at *www.gao.gov/products/GAO-18-25.*

One in Five Drivers Uses a Prescription Drug That Can Impair Driving Despite Receiving Warnings

A new study that analyzes data from the National Roadside Survey of Alcohol and Drug Use, 2013-2014, found that one in five drivers has taken prescription drugs that could impair driving despite having been warned about the risks. The authors of the study, "Receipt of Warnings Regarding Potentially Impairing Prescription Medications and Associated Risk Perceptions in a National Sample of U.S. Drivers," indicate that of the 7,405 random drivers who completed the prescription drug portion of the survey, almost 20% reported recent use (within the past two days) of a potentially impairing prescription drug.

Compared to people who were prescribed antidepressants (62.6%) and stimulants (57.7%), those who were prescribed sedatives (85.8%) and narcotics (85.1%) were most likely to report receiving warnings about the potential of these drugs to affect driving from their health care provider, pharmacy staff, or medication label.

Several European countries have introduced color-coded categories (ie, no, minor, moderate, and major influence on driving) to drug labeling to increase patient safety. Beyond labeling, the authors of the study note it is important that health care providers consistently communicate with patients about their medications' driving-related risks. The study was published online in the *Journal of Studies on Alcohol and Drugs* on October 31, 2017, and can be found at *https://doi.org/10.15288/jsad.2017.78.805.*

PTCB CPhT Program Earns Accreditation From the American National Standards Institute

The Pharmacy Technician Certification Board's (PTCB's) Certified Pharmacy Technician (CPhT) Program has earned accreditation from the American National Standards Institute (ANSI) Personnel Certification Accreditation Program through December 2022. ANSI is the first personnel certification accreditation body in the US to meet internationally accepted practices for accreditation. "We were the first pharmacy technician certification program to receive accreditation by the National Commission for Certifying Agencies (NCCA) in 2006, and now we are the first and only program to achieve ANSI accreditation," said PTCB Executive Director and Chief Executive Officer William Schimmel in a news release. More details are available in PTCB's December 18, 2017 news release, which can be found in the News Room section of *www.ptcb.org.*

Continued from page 1

If the Board grants a licensee/permittee's petition, the relevant records relating to the reprimand previously issued by the Board shall be sealed, subject only to production in response to lawful requests for the same by state or federal agencies, or appropriate third parties. Subject to the aforementioned limited exceptions for producing the records, the records will not be available to the public and will be removed from the Board's website. Further, the proceedings and resulting reprimand shall be deemed by the Board to have not occurred.

Reprimands resulting from the following conduct by individual licensees shall not be eligible for expungement:

(a) offenses involving controlled substance (CS) diversion and abuse or misuse;
(b) offenses in which drugs, including non-controlled and/or CS, were diverted and distributed to a third party;
(c) unlicensed practice; and
(d) practicing while impaired.

Reprimands resulting from the following conduct by permittees shall not be eligible for expungement:

(a) shipping into South Carolina without a permit (nonresident facilities);
(b) permit holders with nonreciprocal and nonrelated offenses; and
(c) offenses involving distribution of misbranded and/or adulterated drugs.

The Board will not consider a petition for expungement until a minimum of one year has passed after the licensee/permittee's satisfactory completion of any conditions imposed by the Board relating to the reprimand sought to be expunged. A licensee/permittee must file a petition for expungement with the Board administrator attesting that the licensee/petitioner's petition falls within the guidelines set forth above. The Board will consider the petition at a later meeting of the Board and determine whether the petition should be granted. The Board will consider each case on its merits and reserves the right to deny any petition for expungement if expungement of the reprimand would not be in the public interest. Petitioner shall be required to attend any hearing involving the petitioner's request.

Board Updates Policy and Procedure #140 – Approved Technician Duties

An employee of a pharmacy holding a pharmacy permit who is not registered with the Board may perform many **clerical** functions associated with the practice of pharmacy. A nonregistered employee is prohibited from performing the following functions:

- Entering data beyond demographic information (name, address, date of birth, gender, contact information, insurance, etc);
- Interpreting prescription drug orders;
- Handling non-dispensed legend drugs or devices; or
- Compounding of any over-the-counter or legend drug.

A registered or certified pharmacy technician may perform many **clerical** functions associated with the practice of pharmacy at a facility holding a pharmacy permit. While fulfilling clerical functions, up to the point of dispensing requiring clinical interpretation and/or product selection, as defined in Section 40-43-30(15) of the South Carolina Code of Laws, registered or certified technicians would not be considered in the pharmacist-to-technician ratio as indicated by Section 40-43-86(B)(4)(b).

A registered pharmacy technician may perform many **technical** functions associated with the practice of pharmacy at a facility holding a pharmacy permit; however, even under the direct supervision of a pharmacist, the pharmacy technician is prohibited from performing the following functions:

- Performing any duty required by law or regulation to be performed by a state-certified technician, pharmacy intern or extern, or a pharmacist;
- Administering immunizations;
- Counseling a patient on a new or refill prescription;
- Performing the final check on all aspects of the completed prescription;
- Conducting or overriding a patient drug utilization review and/or drug interaction alerts; or
- Making clinical decisions based on medication reconciliation or history taking.

The following duties may be performed by a **state-certified** registered technician after the supervising pharmacist carefully considers the individual's abilities and/or qualifications at a facility holding a pharmacy permit:

- Receiving and initiating verbal telephone orders for non-controlled prescriptions.
- Conducting a one-time transfer of a non-controlled prescription. This should in no way prohibit a future transfer of the same prescription.
- Checking a technician's refill of medications if the medication is to be administered by a licensed health care professional in an institutional setting.
- Checking a technician's repackaging of medications from bulk to unit dose in an institutional setting.
- Conducting monthly inspections of non-dispensing drug outlet permit sites, provided that inspection of the site does not require any clinical interpretation or review of patient charts or other patient-specific information, in which case the inspection must be completed by a pharmacist.

A state-certified registered technician may not conduct inspections at any permitted site that engages in compounding. The consultant pharmacist of record shall conduct the inspection of the non-dispensing drug outlet permitted facility no less than every six months. If the inspection is conducted by a state-certified registered technician or another pharmacist, the consultant pharmacist must countersign the inspection form and send it to the non-dispensing permit site to retain for their records. The signed inspection form may be sent electronically. If a state-certified registered technician finds any deficiencies during the inspection, the person of contact at the permitted site must be contacted immediately and the consultant pharmacist must be notified within 24 hours.

As stated in Section 40-43-82(C), ". . . a certified technician is prohibited from checking another technician's fill, refill, or repackaging of medications for delivery to a patient in an outpatient setting."

Board Approves ExCPT Exam

At the March 14, 2018 Board meeting, the Board approved the Exam for Certification of Pharmacy Technicians (ExCPT) as a Board-approved exam to fulfill one of the requirements for state certification for pharmacy technicians.

Clarification Regarding the Transfer of Unfilled CS Prescriptions

The Board has received clarification regarding the transfer of unfilled CS prescriptions. Please see the excerpt below from a memo by Loren T. Miller, associate section chief, Drug Enforcement Administration (DEA), via Carmen Catizone, executive director/secretary, NABP.

> The Controlled Substances Act and its implementing regulations outline what can take place regarding prescriptions for controlled substances. In Title 21, Code of Federal Regulations, Section 1306.25 the DEA made a specific exception so that a DEA registered pharmacy can, once it has filled an original prescription for a controlled substance in Schedules III-V, transfer the original prescription information to another DEA registered pharmacy for the purpose of allowing that second pharmacy to then dispense any remaining valid refills still permitted by law and the prescriber's authorization. With one exception, such an allowance currently does not exist for the forwarding of an unfilled prescription from one DEA registered retail pharmacy so that it may be filled at another DEA registered retail pharmacy.
>
> Prescriptions can take the form of paper (including fax), call-in, or electronic prescription for controlled substances (EPCS). The DEA has addressed the forwarding of an EPCS prescription. The DEA published information in the preamble of the notice of proposed rulemaking (NPRM) on EPCS, 73 FR 36722, and the preamble of the interim final rule (IFR) on EPCS, 75 FR 16235. Note, because this was in the preamble and not in the EPCS regulations, it represents the DEA's policy. As posted in the preambles of the NPRM and the IFR, an unfilled original EPCS prescription can be forwarded from one DEA registered retail pharmacy to another DEA registered retail pharmacy, and this includes Schedule II controlled substances.
>
> At the start of 2017, the DEA received inquiries from some pharmacists regarding this issue. The DEA was advised that these pharmacists had received notice from their management that they could not forward original unfilled prescriptions for controlled substances as there was no exception in Federal regulation that expressly allowed this activity. The pharmacists were provided with the above information. Although the DEA received several inquiries regarding this issue earlier in the year, these have now ceased.

DHEC Bureau of Drug Control's Enforcement Process

By Lisa Thomson, RPh, Director, DHEC Bureau of Drug Control

In response to questions regarding the South Carolina Department of Health and Environmental Control (DHEC) Bureau of Drug Control's enforcement process, the following actions may be taken due to violations of the South Carolina Controlled Substance Act and Regulations *(www.scdhec.gov/Health/FHPF/DrugControlRegisterVerify/RelatedLinks)*.

Letters of Admonition: Letters are sent to the registrant when CS violations are noted during an inspection or audit but do not rise to the level of an administrative conference, or may be utilized for a first-time infraction. The registrant is encouraged to send in a corrective action plan to explain how violations will be corrected.

Administrative Conferences: Conferences are conducted when there are repeated violations found during an inspection or audit. Presentation of views at an administrative conference are informal, and the discussion shall be confined to matters relevant to bringing violations into compliance.

Order to Show Cause/Administrative Consent Order: The show cause conferences are formal in nature and are typically the result of an arrest of a health care practitioner or the repeated theft/loss of CS by a registrant. The result of these orders may include the revocation of a CS registration or a restriction being placed on the registrant's CS registration.

Common violations noted during CS pharmacy inspections are:

- May 1 inventory infractions: inventory not taken, wrong date, no time (open or close) documented, no package size noted on the drug counts, no PIC change inventory
- CS ID logs: type of ID, ID not taken, employee initial, date of sale not documented
- Wrong practitioner entered
- Incorrect prescription date written and entered in the computer system
- Excessive quantities being dispensed (more than the 31 or 90 days supply limitation or dispensing more than authorized)
- Refilling a Schedule II prescription when unable to locate original medication that had been filled but not sold
- Not pulling the on-hold CS prescription before filling and documenting the dispensing pharmacist
- Failure to report theft/loss of CS
- Purchase records: not dated or missing
- Fax requirements not met
- Practitioner is prescribing CS without a registration or beyond the authorization of their registration (for example, nurse practitioners prescribing Schedule II CS)

Please contact the Bureau of Drug Control at 803/896-0636 if you have any questions.

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.

Lee Ann F. Bundrick, RPh, Administrator - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Amy Suhajda - Communications Manager