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News

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

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2019-2020 Technician Renewals

Renewal notices for registered and state-certified pharmacy technicians are open! If you validated your email address with the South Carolina Department of Labor, Licensing, & Regulation – Board of Pharmacy, you can complete the online renewal process. In order to access your renewal online, you will need your user ID and password. The renewal notice email contains a link that will allow you to reset your user ID and password. To make the process smoother for everyone, please make sure your correct email is on file with the Board.

If you do not know your password, visit *https://eservice.llr.sc.gov/SSO/Login/RecoverPass* to change it.

To change your email address, send a request via email to contact.pharmacy@llr.sc.gov. Please allow 24 hours for updates.

If you choose not to renew online, you may request a paper renewal from the Board office and renew by mailing in the completed form and proper fees. Applications for renewal must be filed **before** July 1, 2019, in order to avoid penalty. Beginning July 1, 2019, a penalty will apply. If you do not renew online, please document the date the application is mailed. The Board recommends that 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 after June 30, 2019, must include the renewal fee plus a renewal penalty, in addition to evidence that the applicant meets the renewal requirements.

Pharmacy technicians who do not renew prior to June 30, 2019, will be assessed penalties and cannot work as pharmacy technicians until a 2019-2020 registration is in hand or disciplinary action may result.

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 continuing pharmacy education (CPE) credits. You will be asked to provide your e-Profile ID number on the renewal form. Visit *www.nabp.pharmacy/create* for more information on creating a new e-Profile ID.

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 Board.

To avoid delays in receiving your 2019-2020 registration, you are encouraged to renew at least two weeks prior to the June 30 deadline.

Facility Renewals

Prior to sending out the permit renewal notices, the Board incorporated an email validation process for in-state facilities. The validation email was sent to all last known email addresses associated with each permit. When one email address has been successfully validated, it guarantees the facility's permit renewal notice will be sent electronically rather than through the United States Postal Service. Email validations must have been completed before midnight on March 31, 2019, in order to have the option to renew electronically.

For those who did not validate their email address, or for those facilities located out of state, the permit renewal notices were mailed in early April 2019 to the last known address on file in the Board office. The renewal notice you receive will contain a user ID and, due to security changes, you will be required to reset your password in order to access the online renewal website. If you choose not to renew your permit online, you may download a renewal form from the Board's website at *https://www.llr.sc.gov/POL/Pharmacy.* Mail the completed form and the proper fees to the Board at PO Box 11927, Columbia, SC 29211; or 110 Centerview Drive, Columbia, SC 29210.

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National Pharmacy Compliance News

May 2019

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 Launches Pilot Program to Improve Security of Drug Supply Chain With an Innovative Approach

Food and Drug Administration (FDA) has launched a pilot program allowing participants representing the various parts of the drug supply chain to pilot innovative and emerging approaches for enhanced tracing and verification of prescription drugs in the United States' supply chain. The program is in line with FDA's ongoing efforts to prevent suspect and illegitimate products from entering the supply chain, according to an FDA press release. Eligible manufacturers, repackagers, and other stakeholders can apply to participate in the program, which will inform the development of the enhanced electronic, interoperable track-and-trace system for industry set to go into effect in 2023 in accordance with the Drug Supply Chain Security Act (DSCSA), enacted by Congress on November 27, 2013.

The pilot technologies of this program may become part of FDA's enhanced expectations for reliable track-and-trace systems, which will be designed to reduce diversion of drugs distributed domestically and to keep counterfeit drugs from entering the supply chain. The DSCSA pilot project program is intended to help identify and evaluate the most efficient processes to comply with and apply drug supply chain security requirements and will aid in identifying attributes the system will need for enhanced product tracing and verification, as well as electronic means to share the information. FDA recently issued draft guidance on the use of product identifiers with a unique serial number to improve verification down to the package level. FDA has also provided draft guidance for verification systems to quarantine and investigate suspect and illegitimate drugs.

Additional information on the FDA pilot program is available in a February 8, 2019 announcement in the *Federal Register.*

FDA Announces New Efforts to Increase Oversight and Strengthen Regulation of Dietary Supplements

Noting that three in four Americans now take at least one dietary supplement on a regular basis, and that the dietary supplement industry has expanded to include as many as 80,000 different products for consumers, FDA Commissioner Scott Gottlieb, MD, has announced new plans to increase the agency's oversight of dietary supplements. These initiatives include communicating to the public as soon as possible when there is a concern about a dietary supplement on the market, ensuring that the regulatory framework is flexible enough to adequately evaluate product safety, and continuing to work closely with industry partners. FDA is also developing new enforcement strategies to respond to entities that violate standards established under the Dietary Supplement Health and Education Act of 1994.

On February 11, 2019, FDA sent 12 warning letters and five online advisory letters to foreign and domestic companies that are illegally selling more than 58 products. The products are illegally marketed as unapproved new drugs that make unproven claims about preventing, treating, or curing Alzheimer's disease, as well as a number of other serious diseases and health conditions, such as diabetes and cancer. In his statement, Gottlieb noted that most stakeholders in the industry act responsibly, but he expressed concern over the ability of bad actors to exploit the system by providing potentially dangerous products and making unproven or misleading claims about the health benefits supplements may offer.

FDA is planning a public meeting on this topic during the second quarter of 2019. For more information, view the FDA statement at *https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm631065.htm.*

Trump Administration Releases National Drug Control Strategy to Reduce Drug Trafficking and Abuse

As the opioid crisis continues to claim the lives of tens of thousands of Americans each year, the Office of National Drug Control Policy has released its *National Drug Control Strategy.* The *Strategy* breaks down the administration's priorities in addressing the crisis, with an emphasis on three areas: prevention, treatment and recovery, and reducing availability.

- **Prevention** efforts are focused on educating both consumers and caregivers about the dangers of opioid misuse and include a new national media campaign, continued efforts to expand prescription monitoring programs (PMPs), and improving the ability of state, local, and tribal communities to identify and prevent substance abuse.
- **Treatment and recovery recommendations** in the *Strategy* include improving access to naloxone, improving evidence-based addiction treatment, and eliminating barriers for accessing treatment.

- **Reducing availability** strategies are focused on disrupting illegal supply chains, defeating drug traffickers, increased cooperation with international partners, and combating illegal internet drug sales.

The document notes that the "most important criterion of success" is saving lives and calls for the federal government to work closely with state and local governments, as well as other stakeholders. Additional information, including the full strategy document, is available on the White House website at *https://www.whitehouse.gov/opioids.*

National Association of Boards of Pharmacy® (NABP®) and its member boards of pharmacy remain committed to advancing best practices for PMPs in the interest of public health. NABP's PMP data sharing system, NABP PMP InterConnect®, facilitates the secure transfer of PMP data across state lines and provides an effective means of combating drug diversion and drug abuse nationwide. In addition, NABP and its member boards continue efforts to educate consumers about prescription drug safety. The NABP $AWAR_XE$® Prescription Drug Safety Program's Drug Disposal Locator Tool has more than 6,000 disposal locations and continues to add new locations to provide consumers with a safe way to dispose of medication and help prevent misuse and abuse of prescription medications. For more information about PMP InterConnect and the $AWAR_XE$ program, visit the Initiatives section of the NABP website at *www.nabp.pharmacy.*

New Study Predicts Opioid Epidemic Will Worsen Over the Next Decade

More than 700,000 people will die from opioid overdoses between 2016 and 2025, and annual overdose deaths will reach nearly 82,000 by 2025, estimates a new study published to *JAMA Network Open.* The estimate is based on an analysis of data from the National Survey on Drug Use and Health and the Centers for Disease Control and Prevention from 2002 to 2015.

Researchers also projected that intervention efforts focused on lowering the incidence of prescription opioid misuse would help to reduce the number of deaths 3.8% to 5.3%, a figure the researchers described as "modest," due to the changing nature of the opioid crisis. The study notes that more people are directly initiating opioid use with illicit opioids rather than prescription drugs, and illicit opioids have become more lethal with the availability of illegally manufactured fentanyl.

The researchers encourage policymakers to take "a stronger and multipronged approach" to reduce the impact of the ongoing opioid overdose epidemic. The full article is available at *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2723405.*

FDA Warns of Potential Blood Pressure Medication Shortages Due to Recalls

FDA is warning health care providers and consumers of a shortage of angiotensin II receptor blockers, commonly used to treat high blood pressure. A growing list of medications containing valsartan, losartan, and irbesartan have been recalled from the market for containing an impurity that may present a cancer risk to patients. The issue was first detected in the summer of 2018, according to a statement posted to the FDA website. Since then, FDA has placed a Chinese manufacturer of the active ingredient on import alert to stop their imports, and FDA is working with other manufacturers to recall affected medications.

In the statement, FDA notes that the risk to individual patients remains very small, but that there is still reason to be concerned about the potential health risks. Medications with these impurities are believed to have been in the market for about four years.

"Now that these risks are identified, we're applying what we've learned to the evaluation of similar manufacturing processes where we now know these risks could arise," the statement notes. The FDA press release is available at *https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm629796.htm.*

FDA Releases Two Draft Guidances Related to REMS Programs

FDA has released two new draft guidances to ensure risk mitigation programs put in place for certain drugs and biologics, as required for approval, are working. The agency's primary risk management tool is FDA-approved product labeling. However, in limited cases, FDA may require a Risk Evaluation and Mitigation Strategy (REMS) to help ensure a drug's benefits outweigh its risks.

The following guidances relate to the assessment of REMS programs:

- **REMS Assessment: Planning and Reporting Guidance for Industry** describes how to develop a REMS Assessment Plan.
- **Survey Methodologies to Assess REMS Goals That Relate to Knowledge Guidance for Industry** provides recommendations on conducting REMS assessment surveys to evaluate patient or health care provider knowledge of REMS-related information.

FDA states that the goal in providing this guidance for REMS is to ensure constant improvement of their safety programs and establish the most efficient and effective programs moving forward, to optimize patient care and keep consumers safe and healthy. More information on REMS is available on the FDA website at *https://www.fda.gov/drugs/drugsafety/rems.*

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All applications must be received at the Board's office prior to June 1, 2019, or a $50 late fee will be assessed. After June 30, 2019, the facility permit will lapse. Upon applying for reinstatement, the facility will be assessed a penalty of $10 per day until the permit is reinstated, plus the $50 late fee and the initial renewal 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 South Carolina Pharmacy Practice Act for operating without a permit, pursuant to Section 40-43-83 of the South Carolina Pharmacy Practice Act, resulting in discipline.

If you are a permit holder and have not received your permit renewal notice or you have additional questions, contact the Board office immediately at contact .pharmacy@llr.sc.gov.

Continuing Education

There has been much conversation and confusion regarding the requirements for pharmacist continuing education, specifically around South Carolina Pharmacy Practice Act Section 40-43-130(B), which states in part, "At least fifty percent of the total number of hours required must be in drug therapy or patient management . . ." The Board had a robust discussion on this topic at the January 2019 meeting. After this discussion, it is evident that there are some CPE activities that meet the drug therapy and patient management criteria but are categorized with the "general" topic designator.

The Board's ultimate guidance is that the content of a CPE activity will be the focus of the determination, not the assigned Accreditation Council for Pharmacy Education topic designator. Any questions can be sent to contact .pharmacy@llr.sc.gov.

Designated Prescriber Lines on South Carolina Prescriptions

According to Section 40-43-86(H)(3) of the South Carolina Pharmacy Practice Act, any prescription that originates in South Carolina is required to have two signature lines for prescribers. Under the line at the left side of the prescription, "Dispense as Written" should be clearly printed. Under the line at the right side, "Substitution Permitted" should be clearly printed.

Prescriptions that originate from another state do not have to meet these requirements. However, if a prescription for a controlled substance originates from out of state, pharmacists should call the physician to verify that it is a valid prescription, and then document that on the hard copy of the prescription.

CBD Oil in Food Products

Food and Drug Administration (FDA) has made a ruling regarding the addition of cannabidiol (CBD) oil in food products and supplements. Numerous states, including South Carolina, are responding accordingly. Please see the below information from FDA. Additional information will be forthcoming from the South Carolina Department of Agriculture.

Under Section 301(ll) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), it is prohibited to introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which has been added a substance that is an active ingredient in a drug product approved under 21 United States Code §355 (Section 505 of the FD&C Act) or a drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public. There are exceptions, including when the drug was marketed in food before the drug was approved or before the substantial clinical investigations involving the drug had been instituted, or in the case of animal feed, when the drug is a new animal drug approved for use in feed and used according to the approved labeling.

However, based on available evidence, FDA has concluded that none of these exceptions are the case for tetrahydrocannabinol (THC) or CBD. FDA has therefore concluded that it is a prohibited act to introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which THC or CBD has been added. FDA is not aware of any evidence that would call into question these conclusions.

Interested parties may present FDA with any evidence that they think has bearing on this issue. The Board's continuing review of information that has been submitted thus far has not called the Board's conclusions into question.

Immunization Kits

Recently, Board inspectors have discovered numerous violations regarding what emergency kits contain at pharmacies that administer immunizations. As a reminder, all pharmacies that administer immunizations must have the items listed in this *Newsletter* in their kits at all times. If any of these items are missing, the administration of all vaccines should cease until the emergency kit can be completely restocked.

1. A current copy of the immunization protocol
2. A supply of the most current federal Vaccine Information Statements for vaccines being administered, or electronic access to these statements

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3. Aqueous epinephrine USP (1:1000) in ampules, vials of solution, or prefilled devices, ie, an EpiPen® (If an EpiPen is to be stocked, at least four adult EpiPens, delivering a single dose of 0.3 mg per 0.3 mL, should be available.)
4. Diphenhydramine (Benadryl®) injectable solution (50 mg per mL) and oral 25 mg dosage form, to include tablets, capsules, or liquid
5. 1-mL and 3-mL syringes, 22-gauge and 25-gauge needles, and 1-inch and 1.5-inch needles for epinephrine and diphenhydramine
6. Alcohol swabs and bandages
7. A blood pressure monitoring device or a stethoscope and sphygmomanometer (with pediatric, adult, and extra-large cuffs)
8. Adult and pediatric size pocket masks with a one-way valve
9. A flashlight with extra batteries (for mouth and throat examination)
10. A timekeeping device with the ability to count seconds
11. Telephone access
12. Equipment, such as a mat or a reclining chair, to enable a person receiving a vaccination to sit or lie down if he or she experiences an adverse reaction to the vaccine

Failure to have a completely stocked (and up-to-date) immunization kit can lead to a citation for the PIC that includes a monetary fine per Board Regulation 99-45. Administrative Citations and Penalties.

Citations

- If a drug item is missing or expired, there may be a $500 citation per drug (for the PIC).
- If there are two or more non-drug related violations, there may be a $500 citation (for the PIC).
- If there are no drugs or all the drugs are expired, the citation may be sent to committee for a recommendation.

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