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News

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

Published to promote compliance of pharmacy and drug law

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2019 Pharmacist Renewal Notices Are on the Way!

Renewal notices for pharmacists are coming soon. The renewal notices for 2019-2020 will be **emailed** in early February, **if** you validated your email address with the South Carolina Department of Labor, Licensing, & Regulation – Board of Pharmacy. In order to access your renewal online, you will need to have your user ID and password. The email renewal will contain a link that will allow you to reset your user ID and password. To make the process smoother for all, please make sure your correct email is on file with the Board.

If you choose not to renew online, you may request a paper renewal form from the Board office and renew by mailing in the completed form and proper fees. Applications for renewal must be filed no later than March 31, 2019, in order to avoid penalty. 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 between April 1 and April 30, 2019, must include the renewal fee plus a $50 renewal penalty, in addition to evidence that the applicant meets the renewal requirements. If you do not renew your license by April 30, 2019, it will be considered lapsed. You can be disciplined for unlicensed practice if you work in South Carolina with a lapsed license.

When renewing, you must indicate that 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. At least one hour must be related to the approved procedures for monitoring the controlled substances listed in Schedules II, III, and IV of the schedules provided for in Sections 44-53-210, 44-53-230, and 44-53-250 of the South Carolina Code of Laws. If you are a pharmacist who administers immunizations, you must complete at least one hour of Category 1 continuing medical education or Accreditation Council for Pharmacy Education (ACPE)-accredited continuing pharmacy education (CPE) related to the administration of vaccines as part of your annual licensure requirements. Please make sure your CE fits into one of these two categories. You cannot renew until you have completed the CE requirements. A random CE audit will be conducted on 10% of renewals after they are processed. Please respond promptly if you are selected for the audit. Disciplinary action may be taken if you cannot show you completed the CE requirements or if proof of the required CE is dated after your renewal is received by the Board office.

Please note, if this is your first renewal since receiving your license, you are exempt from the CE requirements.

Anatomy of an ACPE UAN

Per the ACPE website, a Universal Activity Number (UAN) is an identification assigned to each CPE activity developed and provided, or jointly provided, by an ACPE-accredited provider. In this example ACPE UAN:

#1234-0000-12-123-**L03-P**

- L indicates live CPE activity; H would indicate home study activity.
- 03 is the topic designator for Law (all ACPE topic designators are listed below).
- P indicates the activity's target audience is pharmacists; T would indicate pharmacy technicians.

ACPE UAN Topic Designators

- 01 – Disease/Drug Therapy Related
- 02 – HIV/AIDS Therapy Related
- 03 – Law
- 04 – General Pharmacy Topics
- 05 – Patient Safety
- 06 – Immunizations
- 07 – Compounding

Upcoming Fee Increases

After months of due diligence, discussion, and public comment, the Board voted to increase application and renewal fees. Effective March 1, 2019, there will be a 40% increase in application and renewal fees for all facilities.

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National Pharmacy Compliance News

February 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.

Final Guidance Documents Address FDA Policies Related to DSCSA

To help ensure that prescription drug products are identified and traced properly as they move through the supply chain in compliance with federal law, Food and Drug Administration (FDA) issued two final guidance documents related to the Drug Supply Chain Security Act (DSCSA). Released on September 19, 2018, the following final guidance documents will help ensure there are no disruptions in the supply chain as manufacturers and repackagers include a product identifier on the package or case.

- *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy* addresses industry-wide readiness for implementation of the new requirements aimed at enhancing the security of the drug supply chain. As the agency continues to work with stakeholders to ensure proper implementation of the law, this guidance document specifies FDA's one-year delay in enforcing the manufacturers' requirement to include a product identifier on the package or case of products to November 27, 2018.
- *Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier* outlines the circumstances in which packages and cases of product that were in the supply chain before the November 2018 product identifier requirement are considered grandfathered. The grandfathering policy describes the circumstances under which products already in the supply chain can remain in distribution without being relabeled with a product identifier.

The final guidance documents can be found at *www.fda.gov/newsevents/newsroom/fdainbrief/ucm621095.htm.*

First FDA-Approved Drug Containing Extract From Cannabis Plant to Be Placed in Schedule V

On September 27, 2018, the United States Department of Justice and Drug Enforcement Administration (DEA) announced that Epidiolex® – which contains cannabidiol, a chemical constituent of the cannabis plant, and is the first FDA-approved drug to contain a purified extract from the plant – is being placed in Schedule V of the Controlled Substances Act. FDA approved Epidiolex for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older on June 25, 2018. Additional information is available in the announcement at *www.dea.gov/press-releases/2018/09/27/fda-approved-drug-epidiolex-placed-schedule-v-controlled-substance-act.*

ASHP Guidelines Provide Recommendations for Preventing Patient Harm From Medication Errors

New guidelines from the American Society of Health-System Pharmacists (ASHP) describe opportunities for pharmacists on interprofessional teams to prevent errors across the continuum of care in hospitals and health systems. The "ASHP Guidelines on Preventing Medication Errors in Hospitals" are intended to apply to the acute care setting because of the special collaborative processes established in this setting. However, these guidelines may be applicable to practice settings outside of the acute care setting, especially in health systems.

Further, the ASHP press release notes that the guidelines address numerous areas in the medication-use process where errors may occur, including: patient admission; selection and procurement; storage; ordering, transcribing, and reviewing; preparation; dispensing; administration; monitoring; evaluation; and patient discharge. Published in the October 1, 2018 issue of the *American Journal of Health-System Pharmacy,* the guidelines are available at *www.ajhp.org/content/75/19/1493.* ASHP's October 2, 2018 press release can be found in the News section at *www.ashp.org.*

FDA's Final Guidance Documents Address Compounding and Repackaging of Radiopharmaceuticals

On September 26, 2018, FDA published the final guidance titled *Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities.* In this final guidance for industry, FDA sets forth its policy regarding compounding and repackaging of radiopharmaceuticals for human use by entities that are registered with FDA as outsourcing facilities. This guidance describes how FDA generally intends to apply section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to radiopharmaceuticals compounded by outsourcing facilities.

In addition, this guidance describes the conditions under which FDA generally does not intend to take action for violations of certain provisions of the FD&C Act when an outsourcing facility repackages radiopharmaceuticals, according to the *Federal Register* notice at *www.gpo.gov/fdsys/pkg/FR-2018-09-26/pdf/2018-20901.pdf.*

At the same time, FDA published the final guidance titled *Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities.* This guidance sets forth FDA's policy regarding compounding and repackaging of radiopharmaceuticals for human use by state-licensed nuclear pharmacies, federal facilities, and other entities that hold a radioactive materials license for medical use issued by the Nuclear Regulatory Commission or by an Agreement State. Because such radiopharmaceuticals are not eligible for exemptions from provisions of the FD&C Act related to the production of drugs, FDA is issuing this guidance to describe the conditions under which it generally does not intend to take action for violations of certain provisions of the FD&C Act when these entities compound or repackage radiopharmaceuticals. More details are available in the *Federal Register* notice at *www.gpo.gov/fdsys/pkg/FR-2018-09-26/pdf/2018-20902.pdf.*

Pharmacy Toolkit Encourages Conversations With Patients About Prescription Opioids

In collaboration with its pharmacy partners and several state pharmacy associations, Allied Against Opioid Abuse (AAOA) developed a Pharmacy Toolkit to help pharmacists engage and educate patients about the safe use, storage, and disposal of pain medicines. The AAOA Pharmacy Toolkit includes resources to help pharmacists raise awareness among patients about their rights, risks, and responsibilities associated with prescription opioids. These resources include: a pharmacy display, patient handout, patient engagement guide, tips for talking with patients and caregivers, prescriber engagement guide, safe storage and disposal training, and social graphics. To learn more about the Pharmacy Toolkit and to obtain these resources, visit AAOA's website at *https://againstopioidabuse.org.*

Biosimilars Added to FIP's Policy on Pharmacists' Right to Substitute a Medication

To account for the emergence of biological medicines and their biosimilars onto the medical landscape, the International Pharmaceutical Federation (FIP) has added biosimilars to its policy on pharmacists' right to substitute one medicine for another. The revised Statement of Policy titled "Pharmacist's authority in pharmaceutical product selection: therapeutic interchange and substitution" includes the core principles of the original statement and the following:

- generic substitution is recommended as part of the pharmacist's dispensing role;
- pharmacists should be provided with bioavailability data by regulatory authorities and manufacturers; and
- a medicine should only be substituted with a product containing a different active ingredient in agreement with the prescriber.

According to FIP's October 2, 2018 press release, the use of generic names is still encouraged, but the revised statement gives focus to the use of international nonproprietary names. The full Statement of Policy and press release are available at *www.fip.org* in their respective sections.

FDA Offers CE Course on Reducing Hypoglycemic Events in Patients With Type 2 Diabetes

FDA is offering a free, one-hour continuing education (CE) course for health care providers (physicians, pharmacists, nurses, and others) about the reduction of hypoglycemic events in patients with Type 2 diabetes. The course, *Leveraging Health Literacy and Patient Preferences to Reduce Hypoglycemic Events in Patients with Type 2 Diabetes,* will describe the prevalence of hypoglycemic events and identify risk factors leading to an event. Available for credit through October 31, 2020, this course will introduce methods of assessing health literacy and numeracy of patients and caregivers; review effective ways to incorporate patient preferences into care plans; and list action steps to reduce the likelihood of a hypoglycemic event for high-risk patients. To participate in this CE course, visit *http://fdapasediabetes.e-paga.com.*

The FDA Center for Drug Evaluation and Research (CDER) is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education (CPE). This program meets the criteria for one contact hour (0.1 CEU) of CPE credit. The ACPE Universal Activity Number for this knowledge-based activity is 0453-9999-17-449-H01-P. Further, FDA's CDERLearn in the CDER offers a variety of learning opportunities, which can be found at *www.fda.gov/Training/ForHealthProfessionals/ucm545645.htm.*

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Beginning July 1, 2019, there will be a 40% increase in application and renewal fees for all pharmacists and technicians.

This is the first increase in more than 20 years.

The decision to increase fees was not one that the Board made lightly. The Board spent a significant amount of time examining the budget and operating expenses to determine any opportunities for efficiencies. The Board looked at various scenarios and weighed the long-term impact each scenario would have on the licensees as well as the operating budget. The decision for a 40% increase was based on the lowest increase possible while still remaining sustainable for the foreseeable future.

While no one wants to have increased fees, the increased cost of doing business mandates the need for increased revenue. The increased fee structure approved by the Board is commensurate with pharmacy licensure and permit fees in neighboring states and allows the Board to continue maintaining value-added services, such as all pharmacist inspectors, which many states do not have.

	Current Fee	New Fee as of July 1
RPh New Application	$70	$98
RPh Renewal	$70	$98
Technician New Application	$40	$56
Technician Renewal	$15	$21

Community Distributor Protocol

The "Joint Protocol for Certain Community Organizations to Distribute Naloxone" went into effect on November 14, 2018. This joint protocol authorizes:

1. Prescribers practicing in the state of South Carolina to directly, or by standing order, prescribe naloxone hydrochloride products to a community distributor.
2. Pharmacists licensed by the Board to dispense the products to a community distributor pursuant to a prescription or a standing order.
3. Community distributors to distribute the naloxone hydrochloride products.

In order to be a community distributor, an organization must be vetted and approved by the Department of Alcohol and Other Drug Abuse Services (DAODAS). Approved organizations will receive written notification from DAODAS authorizing them to be a community distributor. There is no quantity limit for the prescription or standing order.

A copy of the joint protocol can be found by visiting *www.llr.sc.gov/pol/medical/pdf/laws/joint_naloxone_protocol.pdf.*

What it Means to Be a PIC

Board staff is often asked about the expectations and responsibilities of being a pharmacist-in-charge (PIC). According to South Carolina Code of Law Section 40-43-30(66), "pharmacist-in-charge" means a pharmacist currently licensed in South Carolina who accepts responsibility for the operation of a pharmacy in conformance with all laws pertinent to the practice of pharmacy and the distribution of drugs and who is in full and actual charge of the pharmacy and personnel.

Some duties of the PIC include ensuring all staff (pharmacists, technicians, and interns) employed at the pharmacy are currently licensed, certified, or registered, and that they all wear proper identification. It is also the responsibility of the PIC to file any necessary reports as well as respond to any violations. Another responsibility is the establishment and implementation of appropriate policies and procedures.

A pharmacist may not serve as PIC unless he or she is physically present in the pharmacy a sufficient amount of time to provide supervision and control. The Board has defined this as a minimum of 50% of the time the pharmacy is open, realizing this is not possible with some pharmacies (ie, 24-hour pharmacies).

Workplace Conditions

The Board held its kickoff meeting regarding workplace conditions on December 5, 2018. The committee/task force consists of members of various practice settings. The members range from management to staff employees. A member of the academic community and a public member also serve with the group. In addition to all meetings being open, pharmacists can voice their concerns via letters or emails. Letters can be sent to:

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