February 2020

News

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

Published to promote compliance of pharmacy and drug law

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https://www.llr.sc.gov/bop • 803/896-4700

2020 Pharmacist Renewal Notices

The renewal notices for 2020-2021 were **emailed** in early February **if** you validated your email address with the South Carolina 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 the completed form and proper fees. If mailed, the Board must receive the application **before** April 1, including all required fees, data, and certification of acceptable continuing education (CE). If not postmarked **before** April 1, a penalty of $50 must be assessed. Please plan accordingly as there are times where incorrect answers stop the process and cause the renewal to be late.

Applications submitted for renewal between April 1 and April 30, 2020, 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, 2020, 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 annual requirement of 15 hours of 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 (CS) 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 (CME) or Accreditation Council for Pharmacy Education (ACPE)-accredited continuing pharmacy education related to the administration of vaccines as part of your annual licensure requirements. Please make sure your CE meets all the specific requirements outlined above. You cannot renew until you have completed the CE requirements. A 10% random CE audit will be conducted after renewals 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. See below for additional information on CE requirements.

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

Pharmacist CE Requirements Overview

The ability to carry over an excess of hours from one year to the next often causes quite a bit of confusion among licensees when it comes to calculating CE hours.

Per South Carolina Code of Laws Annotated §40-43-130, pharmacists must complete 15 hours of ACPE-accredited or CME Category 1 CE **per renewal year.** Any hours in excess of the 15 per renewal year may be carried over to the next renewal; however, they may not be carried over more than one license year. It is the responsibility of the licensee to determine which hours would be used for a current renewal period and which hours would be carried over. Upon audit, if using hours carried over from the previous renewal year, the licensee must submit documentation of hours used for the previous renewal plus the hours being used for the current renewal.

For example, in July 2018, Pharmacist John Que attended a live CME Category 1 training at the hospital where he is employed. The training was accredited for 20 hours and covered drug therapy, opioid monitoring, and

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National Pharmacy Compliance News

February 2020

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.

DEA Proposes New Regulations to Address Opioid Epidemic

Drug Enforcement Administration (DEA) has announced proposed regulations to improve the agency's ability to oversee the production of opioids and other potentially dangerous drugs. The proposed regulation would further limit the quantities of medications that might be vulnerable to diversion and misuse. The proposal would also amend the manner in which DEA grants quotas to certain registered manufacturers to levels aligned with current manufacturing standards aimed at promoting quality and efficiency while also ensuring the country has sufficient quantities of Schedule II controlled substances (CS) necessary for medical, scientific, research, and industrial needs.

The proposal introduces several new types of quotas that DEA would grant to certain DEA-registered manufacturers. These use-specific quotas include quantities of CS for use in commercial sales, product development, packaging/repackaging and labeling/relabeling, or replacement for quantities destroyed. These quotas are intended to improve DEA's ability to respond quickly to drug shortages.

The proposed changes build on 2018 regulatory changes that gave a role to state attorney generals and other federal agencies in setting the aggregate production quotas for Schedule I and II CS. The proposed regulations are available in the October 23, 2019, *Federal Register* announcement at *https://www.federalregister.gov/documents/2019/10/23/2019-21989/management-of-quotas-for-controlled-substances-and-list-i-chemicals*.

FDA Issues Report on Root Causes and Solutions to Drug Shortages

Food and Drug Administration (FDA) has released a new report, *Drug Shortages: Root Causes and Potential Solutions,* which identifies root causes for drug shortages and recommends three "enduring solutions" to address the shortages. These recommendations include:

- creating a shared understanding of the impact of drug shortages on patients and the contracting practices that may contribute to shortages;
- developing a rating system to incentivize drug manufacturers to invest in quality management maturity for their facilities; and
- promoting sustainable private sector contracts (eg, with payers, purchasers, and group purchasing organizations) to make sure there is a reliable supply of medically important drugs.

In addition to these recommendations, the report outlines the agency's ongoing initiatives to mitigate drug shortages and legislative proposals in President Donald J. Trump's Fiscal Year 2020 budget. FDA also highlighted the need for international action, including global implementation of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use's (ICH's) *ICH Guideline Q12: Technical and Regulatory Consideration for Pharmaceutical Product Lifecycle Management,* which provides opportunities for regulatory flexibility in making post-approval changes to the product or its manufacturing process.

"We hope that the recommendations set forth in this report will help to set a framework that all stakeholders can assess and implement as we work together to further mitigate the public health impact that drug shortages have on American consumers," FDA stated. "In the meantime, the FDA's employees remain committed to working behind-the-scenes to anticipate and help mitigate shortages and make sure that patients have access to the drugs they need."

FDA's full statement is available at *https://www.fda.gov/news-events/press-announcements/statement-fdas-new-report-regarding-root-causes-and-potential-solutions-drug-shortages*.

HHS Announces Guide for Appropriate Tapering or Discontinuation of Long-Term Opioid Use

The United States Department of Health and Human Services (HHS) has published a new guide for clinicians intended to provide guidelines for tapering or discontinuing long-term opioid use. The guide, titled *HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics*, covers important issues to consider when changing a patient's chronic pain therapy. The guide also lists issues to consider prior to making a change, when initiating the change, and as a patient's dosage is being tapered, including the need to treat symptoms of opioid withdrawal and provide behavioral health support.

"Care must be a patient-centered experience. We need to treat people with compassion, and emphasize personalized care tailored to the specific circumstances and unique needs

of each patient," said ADM Brett P. Giroir, MD, assistant secretary for health in a press release. "This Guide provides more resources for clinicians to best help patients achieve the dual goals of effective pain management and reduction in the risk for addiction."

FDA Releases Draft Best Practice Document for Postmarket Drug Surveillance

As part of FDA's efforts to enhance the efficiency of its postmarket drug safety surveillance, the agency has released a new best practices document, *Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff*. The draft document outlines FDA's approach for timely postmarket analyses of drugs and biologics, and includes a high-level overview of tools, methods, and signal detection and evaluation activities, using varied data sources, for drug safety. The goal is to provide a broader context and a general overview of ongoing efforts and commitments.

"Our best practices document incorporates the guiding principle that postmarket safety surveillance is a dynamic and constantly evolving field," FDA said in a statement announcing the document's release. "By using a risk-based approach, the FDA takes into account the nature of the drug, its potential adverse events, the intended population, and the potential for serious outcomes, as well as the impact on individuals and the overall potential impact on the health of the public."

The full draft document can be accessed at *https://www.fda.gov/media/130216/download*.

FDA Issues Revised Draft Guidance on Regulation of Homeopathic Products, Withdraws 1988 Compliance Policy Guide

FDA is taking two new steps to clarifying their approach to regulating drug products labeled as homeopathic: revising draft guidance previously published in 2017, and withdrawing the Compliance Policy Guide (CPG) 400.400 issued in 1988. These moves were announced in a statement published on the FDA website. Homeopathic products are often marketed as natural alternatives to approved prescription and nonprescription products and are widely available in the marketplace. Homeopathic products, however, are marketed without FDA review and may not meet modern standards for safety, effectivity, quality, and labeling. FDA uses a risk-based approach to monitor these products and to evaluate reports of adverse events.

The revisions to the 2017 draft guidance provide further information about FDA's approach. The guidance details a risk-based enforcement policy prioritizing certain categories of homeopathic products that could pose a higher risk to public health. These include products with particular ingredients and routes of administration, products for vulnerable populations, and products with significant quality issues. FDA has invited public comment on the guidance before it is finalized. The full guidance and instructions for providing comment are available in the *Federal Register* announcement.

CPG 400.400, Conditions Under which Homeopathic Drugs May be Marketed, is being withdrawn due to inconsistency with the agency's risk-based approach to regulatory and enforcement action and is therefore being withdrawn. Specifically, FDA states that it has encountered multiple issues with homeopathic drug products posing significant risk to patients, even though the products, as labeled, appeared to meet the conditions of CPG 400.400.

DEA Warns of Increase in Scam Calls Targeting Pharmacists and Other DEA-Registered Providers

DEA is warning health care providers and other members of the public of another increase in fraudulent phone calls attempting to extort money. Though the tactics change regularly, the callers typically claim to represent DEA and provide either fake names and badge numbers, or the names of well-known senior officials with DEA. The scammers then threaten legal action, including arrest, against the victim unless large fines are paid by wire transfer. Most recently, the scammers appear to be spoofing a DEA number based out of Salt Lake City, UT, according to a DEA press release.

The agency emphasizes that DEA will never contact practitioners by phone to demand money or any form of payment. DEA will not request any personal or sensitive information by phone, and notification of a legitimate investigation or legal action is always made via official letter or in person.

DEA asks anyone who receives a call from a person purporting to be a DEA special agent or other law enforcement official asking for money to refuse the demand and report the threat using the online form or by calling 877/792-2873. Reporting these calls will assist DEA in investigating and stopping this activity.

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immunizations. Upon renewal in March 2019, John Que used 15 of those hours for his 2019 renewal. This left five hours that John Que could carry over toward the required 15 hours for the 2020 renewal. Upon audit in 2020, John Que was able to show which hours were used for the 2019 renewal and which hours were used for the 2020 renewal, totaling 30 hours for the two years.

Other reminders include:

- Of the required 15 hours, a minimum of six must be "live" as indicated by the ACPE Universal Activity Number
- Fifty percent of the total (7.5 hours) must be in patient management or drug therapy
- At least one hour related to approved procedures for monitoring CS
- At least one hour related to administration of immunizations for those pharmacists who immunize

Changes Are Coming!

The following article has been reprinted from PTCB with minor edits.

Please see below for information from the Pharmacy Technician Certification Board (PTCB). This does not change any South Carolina-specific criteria in regard to state certification.

New PTCB Requirements Take Effect in 2020

We have some important information about PTCB's upcoming changes to Certified Pharmacy Technician (CPhT) eligibility requirements and the Pharmacy Technician Certification Exam (PTCE) content blueprint.

CPhT Certification Applicants Must Meet New Requirements

Starting in 2020, PTCB is changing requirements for the CPhT program and updating the PTCE. PTCB will require individuals to complete a PTCB-recognized education/training program **or** have equivalent work experience to be eligible to apply for the CPhT credential.

Pharmacy Technician Educators Must Become Recognized

Education/training programs for pharmacy technicians must become PTCB-recognized to ensure that their students are eligible to take the PTCE after they complete the program.

- As of January 1, 2020, if a program is not PTCB-recognized, its students will not be eligible to test.
- The process to become PTCB-recognized is easy and there is no cost.
- To be recognized, a program must attest that its curriculum includes PTCB-required knowledge. This knowledge is identified in PTCB's new PTCE 2020 exam blueprint.

Accreditation is not required to become a PTCB-recognized education/training program. However, PTCB automatically recognizes programs accredited by the American Society of Health-System Pharmacists, ACPE, or the Accrediting Bureau of Health Education Schools. These accredited programs do not need to submit an attestation.

Elections for Fourth Congressional District

Ballots for the upcoming Board vacancy have been mailed to pharmacists residing in the Fourth Congressional District. Please ensure that you follow the enclosed instructions in order for your vote to count. Any deviation from the stated instructions will cause the ballot to be void. You may only vote for one candidate. Ballots must be postmarked on or before February 15, 2020, and must be received by the Board office no later than February 25, 2020.

Before March 1, 2020, the Board will send the top three names to the governor's office in order for a candidate to be appointed to the seat by the governor. The term is for six years and will run from July 1, 2020, to June 30, 2026.

The Board would like to thank the following individuals for their interest in the Board seat for the Fourth Congressional District:

- Michael Bedenbaugh
- Blake Hawkins
- Eric Strauss
- S. Rochelle Sullivan
- George Edward Vess, Jr

Board Calendar for 2020

The Board invites all licensees and members of the public to attend its public meetings at 110 Centerview Dr, Columbia, SC 29211. The meetings are scheduled to begin at 9 AM. The meeting agenda may be reviewed prior to the meeting at *https://llr.sc.gov/bop/agendas.aspx.*

The 2020 meeting schedule is as follows:

- March 11
- June 10-11
- September 16-17
- November 17

Single-Page DEA Form 222

According to Drug Enforcement Administration (DEA), there has been quite a bit of confusion in the community

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related to the new single-page 222 forms and how to report distributions. Please see the information below.

> The supplier must retain the original [single-page] DEA Form 222 for the supplier's files in accordance with [Title 21 Code of Federal Regulations (CFR),] §1305.17(c). Any supplier who is not required to report acquisition/disposition transactions to the Automation of Reports and Consolidated Orders System (ARCOS) under [21 CFR,] §1304.33(c) (such as a practitioner) **must make and submit a copy of the original DEA Form 222 to DEA, either by mail to the Registration Section, or by email to DEA.Orderforms@usdoj.gov.** The copy must be forwarded at the close of the month during which the order is filled. If an order is filled by partial shipments, the copy must be forwarded at the close of the month during which the final shipment is made or the 60-day validity period expires. (emphasis added)

Any pharmacy that supplies CS using a 222 form (such as distributions to a physician or a reverse distributor) must report as previously highlighted in bold because pharmacies are not required to report their distributions to ARCOS. The triplicate 222 forms are still valid until October 30, 2021, and 21 CFR §1305.13(d) explains the distribution of Copy 2 to DEA for pharmacies still using the triplicate 222 forms. Any pharmacy with questions may call the local DEA office at 803/253-3441.

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