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News

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2021 Renewal Notices Are on the Way for Pharmacists

Renewal notices for pharmacists for 2021-2022 will be **emailed** in early February **if** you validated your email address with the South Carolina Department of Labor, Licensing, & Regulation – Board of Pharmacy. To access your renewal online, you will need 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, 2021, 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 per state law. 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, 2021, must include the renewal fee plus the $50 renewal penalty, in addition to evidence that the applicant meets the renewal requirements. If you do not renew your license by April 30, 2021, 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 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 meets all the specific requirements outlined above. You cannot renew until you have completed the CE requirements. A random CE audit of 10% of licensees 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.

Immunizing Pharmacist CE Clarification

The United States Department of Health and Human Services recently issued declarations under the Public Readiness and Emergency Preparedness Act (PREP Act) authorizing pharmacists to order and administer the Advisory Committee on Immunization Practices-recommended pediatric vaccines and coronavirus disease 2019 (COVID-19) vaccines. This has prompted numerous questions about the CE requirements for immunizing pharmacists under the federal authorization versus CE requirements under South Carolina law. Under the PREP Act declaration, the licensed pharmacist must complete a minimum of **two hours** of ACPE-approved, immunization-related CPE during each state licensing period (annually in South Carolina). This PREP Act declaration CE requirement differs somewhat from South Carolina law. South Carolina Code of Laws Annotated §40-43-190(B)(5) states:

> A pharmacist administering vaccinations shall, as part of the current continuing education requirements pursuant to Section 40-43-130, complete no less than one hour of continuing education each license year regarding administration of vaccinations.

A pharmacist who chooses to exercise authority granted under the PREP Act must slightly increase his or her immunization-related CE and acquire two hours prior to the 2021 renewal.

As a reminder, if a pharmacist chooses to exercise his or her authority under the PREP Act, he or she must follow it in its entirety, not just select portions.

Data Integrity for the Prescription Monitoring Program

By Christie Frick, RPh, PMP Director, South Carolina Department of Health and Environmental Control Bureau of Drug Control

The South Carolina prescription monitoring program (PMP), known as the South Carolina Reporting & Identification Prescription Tracking System (SCRIPTS), is an integral component in the state's fight against the opioid epidemic. With mandatory PMP consultation in our state, improved quality of dispensing data becomes essential. The quality of data sent to the PMP is dependent on the accuracy and completeness of the information provided by the dispenser. There are times when data

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National Pharmacy Compliance News

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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 Publishes New Version of Pharmacist's Manual

The latest version of the *Pharmacist's Manual: An Informational Outline of the Controlled Substances Act* has been released by Drug Enforcement Administration's (DEA's) Diversion Control Division. The guide is provided to assist pharmacists in understanding the Federal Controlled Substances Act and its regulations as they pertain to the pharmacy profession. This edition has been updated to include information on the Secure and Responsible Drug Disposal Act of 2010, the Comprehensive Addiction and Recovery Act of 2016, and the SUPPORT for Patients and Communities Act of 2018, and replaces all versions of the guidance previously issued by the agency. The new *Pharmacist's Manual* can be accessed by visiting the DEA website.

Time to End VinCRIStine Syringe Administration

This column was prepared by the Institute for Safe Medication Practices (ISMP), an ECRI affiliate. Have you experienced a medication error or close call? Report such incidents in confidence to ISMP's National Medication Errors Reporting Program online at www.ismp.org or by email to ismpinfo@ismp.org to activate an alert system that reaches manufacturers, the medical community, and Food and Drug Administration (FDA). To read more about the risk reduction strategies that you can put into practice today, subscribe to the ISMP Medication Safety Alert!® newsletters at www.ismp.org.

At the request of FDA, Pfizer has revised the prescribing information and product packaging for vin**CRIS**tine sulfate injection. Importantly, they have removed wording from the vin**CRIS**tine package insert that described direct intravenous (IV) injection of vin**CRIS**tine via a syringe. FDA recommended this revision at the request of ISMP, the National Comprehensive Cancer Network, and The Joint Commission.

The WARNINGS section of the package insert now states, "To reduce the potential for fatal medication errors due to incorrect route of administration, vin**CRIS**tine sulfate injection should be diluted in a flexible plastic container and prominently labeled as indicated 'FOR INTRAVENOUS USE ONLY—FATAL IF GIVEN BY OTHER ROUTES.'" More than 140 deaths are known to have occurred in the United States and globally due to accidental intrathecal injection of the drug via syringe, often when it was mixed up with, or wrongly assumed it was supposed to be given with, another drug meant for intrathecal administration, such as methotrexate. No such cases have been reported with dilution of vin**CRIS**tine in a minibag, due to physical differences in the packaging and the need for an administration set.

Unfortunately, some practice sites are still using syringes to administer IV vin**CRIS**tine. Based on data collected in response to the *ISMP Medication Safety Self Assessment for High Alert Medications* between September 2017 and March 2018 from 442 US hospitals, nearly 20% of respondents still used syringes at least part of the time, including 13% who always used syringes to administer IV vin**CRIS**tine. Thus, the risk of accidental intrathecal injection still exists in the US and globally.

Dispensing vin**CRIS**tine and other vinca alkaloids in a minibag of compatible solution, and not in a syringe, was among the very first *ISMP Targeted Medication Safety Best Practices for Hospitals,* which were launched in 2014[1]. Then, in March 2019, ISMP called on the FDA to eliminate all mention of syringe administration from official vin**CRIS**tine labeling.[2]

ISMP has frequently referred to wrong route administration of vin**CRIS**tine and vinca alkaloids as the "most serious of all medication errors." Patients experience tremendous pain and are often aware of their impending death, which typically occurs within days or weeks. There is no effective reversal once the mistake is made. Even with the labeling change, there is nothing to stop health care practitioners from administering vin**CRIS**tine via syringe (except if they can only get the drug dispensed in a minibag). We hope that every hospital and health system will investigate exactly how vin**CRIS**tine is being administered at any site that uses the drug. It is time to end the practice of syringe administration by making it a requirement for all vin**CRIS**tine doses to be diluted in a minibag.

References

1. *www.ismp.org/guidelines/best-practices-hospitals*
2. *www.ismp.org/resources/ismp-calls-fda-no-more-syringes-vinca-alkaloids*

What Pharmacists Need to Know About Biosimilar and Interchangeable Biological Products

This column was prepared by FDA, an agency within the US Department of Health and Human Services, that protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines, and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

Biological products are a diverse category of products and are generally large, complex molecules. These products may be produced through biotechnology in a living system, such as a microorganism, plant cell, or animal cell, and are often more difficult to characterize than small molecule drugs. There are many types of biological products approved for use in the US, including therapeutic proteins (eg, filgrastim), monoclonal

antibodies (eg, adalimumab), and vaccines (eg, influenza and tetanus).

Section 351(k) of the Public Health Service Act (PHS Act) provides an abbreviated licensure pathway for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference product, which can help provide more affordable treatment options for patients. For example, on March 23, 2020, FDA-approved insulin products were transitioned to regulation as biological products under the PHS Act, which means that transitioned insulin products are open to competition from future biosimilars, including interchangeable biosimilars.

Key Terms for Biosimilar and Interchangeable Products

- **Biosimilar Product:** A biosimilar is a biological product that is highly similar to and has no clinically meaningful differences from an FDA-approved reference product.
- **Interchangeable Product:** An interchangeable product is a biosimilar that meets additional approval requirements and may be substituted for the reference product without the intervention of the prescribing health care provider.
- **Reference Product:** A reference product is the single biological product, already approved by FDA, against which a proposed biosimilar or interchangeable product is compared.

Are Biosimilars the Same as Generic Drugs?

Biosimilars and generic drugs are versions of brand name drugs and may offer more affordable treatment options to patients. Biosimilars and generics are approved through different abbreviated pathways that avoid duplicating costly clinical trials. But biosimilars are not generics, and there are important differences between them.

For example, the manufacturer of a generic drug must demonstrate, among other things, that the generic contains the same active ingredient as the brand name drug and that the generic is bioequivalent to the brand name drug. By contrast, biosimilar manufacturers must demonstrate that the biosimilar is highly similar to the reference product, except for minor differences in clinically inactive components, and that there are no clinically meaningful differences between the biosimilar and the reference product in terms of safety and effectiveness.

Unlike generics, biosimilars are generally prescribed by brand name by a health care provider, while interchangeables, like generics, may be substituted without the involvement of the prescribing health care provider, depending on state laws.

What is the Purple Book?

The Purple Book database contains information on FDA-licensed (approved) biological products regulated by the Center for Drug Evaluation and Research, including licensed biosimilar and interchangeable products, and their reference products. It also contains information about all FDA-licensed allergenic, cellular, and gene therapy, hematologic, and vaccine products regulated by the Center for Biologics Evaluation and Research .

The Purple Book has simple and advanced search capabilities and some information that you can find includes the proprietary (brand) name and nonproprietary (proper) name of biological products, applicant (company), dosage form, product presentation (eg, autoinjector, vial), route of administration, and strength. The Purple Book also will display FDA-approved interchangeable products and note with which brand product each interchangeable product may be substituted.

Are Therapeutic Equivalence Codes Assigned to Biological Products?

FDA does not assign therapeutic equivalence codes to biological products listed in the Purple Book like it does for small molecule drugs listed in the "Orange Book." The Purple Book provides information about whether a biological product has been determined by FDA to be biosimilar to or interchangeable with a reference product.

Can Interchangeable Products Be Substituted at the Pharmacy?

Many states have laws that address pharmacy-level substitution, including permitting substitution of interchangeable products, and the specific laws vary from state to state.

There are currently no FDA-approved interchangeable products. Once there are, interchangeables, by definition, can be expected to produce the same clinical result as the reference product in any given patient.

Biosimilar and interchangeable products meet FDA's rigorous standards for approval, and patients and health care providers can be assured of the safety and effectiveness of these products, just as they would for the reference product.

Where Can I Find Additional Resources?

- *fda.gov/biosimilars*
- *purplebooksearch.fda.gov*
- *fda.gov/drugs/guidance-compliance-regulatory-information/deemed-be-license-provision-bpci-act*
- *fda.gov/media/135340/download*

Final Insanitary Conditions at Compounding Facilities Guidance Released by FDA

Continuing efforts to protect patients from exposure to poor quality compounded drugs, FDA has published final guidance for compounding facilities regarding insanitary conditions. The final guidance, *Insanitary Conditions at Compounding Facilities Guidance for Industry,* provides recent examples of insanitary conditions that FDA has observed at compounding facilities and details corrective actions that facilities should take when they identify these conditions. The guidance is intended to help compounders identify and prevent such issues at their facilities.

While some compounders work hard to meet quality standards, FDA says its investigators continue to observe poor conditions that impact drug quality and that have the potential to harm patients. These include the presence of dirt, mold, insects, trash, peeling paint, unclean exhaust vents, and dirty high-efficiency particulate air filters.

In response to the draft guidance, FDA states that it has also added recommendations for compounders to use risk management tools to develop appropriate controls to prevent insanitary conditions at facilities. The guidance also addresses the regulatory actions that FDA may take in response to these conditions.

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is entered in the wrong field (eg, the date when a prescription is filled or dispensed may be accidently placed in the patient date of birth (DOB) field), numbers are transposed, or an incorrect DOB is entered. Considering the thousands of data elements most pharmacies record daily, the data provided to the PMP is usually of good quality. However, the slightest error or omission may impact how a patient receives care.

Many of the questions PMP staff receive are from health care providers who cannot find a patient in the PMP. The most common reasons are variations in the patient's name and DOB. Therefore, it is very important that the dispensers be cognizant of what information they have in their pharmacy system. It is best to use a patient's legal name instead of a nickname. Any notes or numbers in the patient name field will transfer to the PMP, making it difficult to find the patient.

Most recently, the Board has gotten many inquiries from veterinarians who cannot locate their patients in the PMP. When filling prescriptions for animals, always use the animal's first name, the owner's last name, and the animal's DOB. Please do not use quotation marks around names or any extra verbiage. For example, many animal prescriptions have a name and "K9" or "dog" included in the first name field. Only the animal's first name should be in the first name field.

To help ensure the best PMP patient searches, please verify the patient's name and DOB are entered correctly in your pharmacy system. Also, having a phone number is extremely helpful when trying to identify patients. Patients will often provide an accurate phone number so that they may be reached if there is a problem with their prescription. Additionally, patients tend to keep the same phone number over longer periods of time even if they move. In that instance, a phone number will be more valuable than a patient address.

The prescribers are now receiving quarterly reports that provide metrics of their prescribing habits of opioids. This report has prompted many prescribers to check their prescribing history in the PMP. It is imperative that special attention is paid to the selection of the appropriate prescriber when filling prescriptions. Prescribers are increasingly finding prescriptions that they did not issue filled under their Drug Enforcement Administration number and name. The majority of these are caused by the dispenser putting the wrong prescriber's name on the prescription. If you are aware of an error, it must be corrected in the PMP as well as in your pharmacy dispensing system. If you are not sure how to make corrections, please contact your corporate office or call the PMP Clearinghouse help desk at 1-844/572-4767 for assistance.

With your assistance in entering complete and accurate information to be transmitted to the PMP, SCRIPTS will continue to be a valuable health care tool to assist providers and dispensers in patient care. Inaccurate information could impede a patient's ability to receive appropriate care.

Prescription accuracy checklist:

- Patient's legal name in name field (no numbers, symbols, nicknames, quotations)
- Correct gender
- DOB
- Phone number
- Suffix in correct field
- Correct prescriber
- For animals: animal's first name, owner's last name, animal's DOB

Increase in Fatal Drug Overdoses Across the United States Driven by Synthetic Opioids Before and During the COVID-19 Pandemic DHEC Health Advisory

Reprinted with permission from the South Carolina Department of Health and Environmental Control

Summary

The purpose of this Health Alert Network (HAN) Advisory is to alert stakeholders to:

(1) substantial increases in drug overdose deaths across the United States, including South Carolina, primarily driven by rapid increases in overdose deaths involving synthetic opioids excluding methadone (hereafter referred to as synthetic opioids), likely illicitly manufactured fentanyl;

(2) a concerning acceleration of the increase in drug overdose deaths, with the largest increase recorded from March 2020 to May 2020, coinciding with the implementation of widespread mitigation measures for the COVID-19 pandemic;

(3) the changing geographic distribution of overdose deaths involving synthetic opioids, with the largest percentage increases occurring in states in the western United States as well as South Carolina;

(4) significant increases in overdose deaths involving psychostimulants with abuse potential (hereafter referred to as psychostimulants) such as methamphetamine; and

(5) recommendations for communities when responding to the evolving overdose crisis.

Background

The most recent provisional data available from the Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics (NCHS) indicate that approximately 81,230 drug overdose deaths occurred in the United States in the 12 months ending in May 2020. This represents a worsening of the drug overdose epidemic in the United States and is the largest number of drug overdoses for a 12-month period ever recorded. Drug overdose deaths during this time increased more than 20% in 25 states and the District of Columbia, this includes South Carolina.

The recent increase in drug overdose mortality began in 2019 and continues into 2020, prior to the declaration of the COVID-19 National Emergency in the United States in March. The increases in drug overdose deaths appear to have accelerated during the COVID-19 pandemic.

Synthetic opioids are the primary driver of the increases in overdose deaths. The 12-month count of synthetic opioid deaths increased 38.4% from the 12 months ending in June 2019 compared with the 12 months ending in May 2020. Of the 38 jurisdictions with available synthetic opioid data, 37 jurisdictions reported increases in synthetic opioid overdose deaths for this time period. Eighteen of these jurisdictions reported increases greater than 50%; this includes South Carolina.

CDC released a HAN on this topic on December 17, 2020, and the full text can be accessed at *https://emergency.cdc.gov/han/2020/han00438.asp.*

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Recommendations

These newly released provisional fatal overdose data, coupled with the known disruption to public health, healthcare, and social services as a result of the COVID-19 pandemic and related mitigation measures, highlight the need for essential services to remain accessible for those most at risk of overdose and the need to expand prevention and response activities. CDC recommends the following actions as appropriate based on community needs and characteristics:

1. Expand the provision and use of naloxone and overdose prevention education

Community-Based Organizations:

- Raise awareness about the critical need for bystanders to have naloxone on hand and use it during an overdose.
- Increase awareness about the risk of using drugs when alone and emphasize the need for risk reduction strategies among people who use drugs, including during the COVID-19 pandemic.
- Increase the provision of overdose prevention education and take-home naloxone.

Healthcare Providers:

- Prescribe naloxone to individuals at risk for opioid overdose, such as those with a prior history of overdose, those with opioid use disorder, and individuals using illicit opioids and other drugs that might be mixed with illicitly manufactured fentanyl.
- Co-prescribe naloxone to patients with high morphine milligram equivalents and those receiving opioids and benzodiazepines.
  - ◊ Expand locations in which overdose prevention education and take-home naloxone are provided, especially in rural areas.

2. Expand access to and provision of treatment for substance use disorders

Healthcare providers:

- Provide Medications for Opioid Use Disorder (MOUD). Treatment with the FDA-approved medications methadone, buprenorphine, or naltrexone are lifesaving and the most effective forms of treatment for opioid use disorder.
- Provide Stimulant (Cocaine, Methamphetamine) Use Disorder Treatment. Unlike opioid use disorder treatment, there are no FDA-approved medications to treat stimulant use disorders, but other therapies have demonstrated effectiveness. For additional information about treatment strategies, see SAMHSA's Treatment for Stimulant Use Disorders.
- South Carolina recently established the SC HOPES support line to help individuals seek resources for increased symptoms of mental health or substance abuse issues related to the COVID-19 crisis. The statewide support line, which can be reached 24/7 at 1-844-SC-HOPES (724-6737) will connect callers to trained clinicians who can address their specific needs. Share information about this resource widely.

3. Intervene early with individuals at the highest risk for overdose

Harm reduction organizations:

- Link people who are at risk for overdose with care and track their retention in care programs. People who are at risk include those who have recently been treated for a non-fatal overdose. Consider expanding peer navigator programs or using recovery coaches.

Healthcare providers:

- Provide active referral-to-treatment options and recovery support services.
- Implement post-overdose response protocols, including in emergency departments, that incorporate links between public health, treatment providers, community-based service organizations, and healthcare providers. These protocols promote overdose education, treatment, linkage to care and MOUD, and naloxone distribution.
- Initiate or continue medications for opioid use disorder among people leaving correctional and detention facilities.

4. Improve detection of overdose outbreaks due to fentanyl, novel psychoactive substances (e.g., fentanyl analogs), or other drugs to facilitate an effective response

Medical examiners and coroners:

- Screen specimens using an enzyme-linked immunosorbent assay (ELISA) test that can detect substances including fentanyl and fentanyl analogs.
- Screen for novel psychoactive substances prevalent in your region or when an unexplained increase in drug overdoses occurs.

Harm reduction organizations:

- Partner with public safety and public health to obtain and disseminate the latest information on local drug supply and overdose trends using tools like the Overdose Detection – Mapping Application Program (ODMAP).

Resources for Additional Information

- Full CDC HAN, Increase in Fatal Drug Overdoses Across the United States Driven by Synthetic Opioids Before and During the COVID-19 Pandemic: *https://emergency.cdc.gov/han/2020/han00438.asp*
- SC, Access to Naloxone: *http://naloxonesavessc.org*
- SC, Screening, Brief Intervention, and Referral to Treatment (SBIRT) model: *http://scsbirt.com*
- SC, Finding Help: *http://justplainkillers.com/find-help/*
- SC, Safe Medication disposal sites for unused prescriptions: *http://justplainkillers.com/drug-safety/*
- SC, SC HOPES support line was established to help residents with substance use or mental health issues related to COVID-19: 1(844)SC-HOPES (724-6737)

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