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North Carolina Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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Item 2379 – Board Publishes Proposed Amendments to the Rules Governing Pharmacist-Manager Responsibilities and RN Dispensing at Health Departments

The North Carolina Board of Pharmacy has published proposed amendments to two existing rules for notice and comment.

Board Rule 21 North Carolina Administrative Code (NCAC) 46.2403 authorizes registered nurses (RNs) at state health departments to dispense certain medications. The state health director has asked the Board to add over-the-counter (OTC) nicotine replacement therapies to the list of drugs that RNs in local health department clinics may dispense pursuant to this rule. The state health director intends to promote nicotine replacement therapies through the North Carolina Department of Health and Human Services' (DHHS) Tobacco Prevention and Control Branch. The state health director has indicated that, among other things, adding OTC nicotine replacement to the list of drugs in this rule will more readily permit the Tobacco Prevention and Control Branch to implement its programs with the North Carolina Medicaid population. The Board is proposing amending the rule as requested by the state health director.

Board Rule 21 NCAC 46.2502 sets forth certain obligations of pharmacist-managers. This rule currently states that a pharmacist-manager may only serve in that capacity on one full-service pharmacy permit. The Board has proposed amending the rule to permit a pharmacist to continue to serve as the pharmacist-manager at one pharmacy while also serving as the pharmacist-manager for a newly permitted pharmacy during the time that the newly permitted pharmacy has not yet begun providing pharmacy services to patients. The Board recognizes that newly permitted pharmacies will often take time to prepare to provide pharmacy services to patients. It wishes to accommodate that process by allowing a person to continue serving as a pharmacist-manager elsewhere while also preparing the newly permitted pharmacy to provide pharmacy services to patients.

The comment period for both proposed amendments is open through January 15, 2019. The Board will hold a public hearing on these proposed amendments at its meeting that same day. For more information on the proposed amendments, as well as instructions on how to file comments, visit *www.ncbop.org/rulemakings.htm.*

Item 2380 – 2018 Licenses, Permits, and Registrations Are Now Expired; 60-Day "Grace Period" Clock Is Ticking!

All licenses, permits, and registrations that the Board issues expire on December 31 each year. Accordingly, if you are reading this *Newsletter* and you did not renew your license, permit, or registration – it has expired.

Do not despair, however. North Carolina law provides that you are not liable for unlicensed practice of pharmacy if you renew within 60 days of your license, permit, or registration expiring. So, if you renew by March 1, 2019, you are safe.

Log in to your account(s) using the Board's licensure gateway, *https://portal.ncbop.org,* and complete your renewal(s). The Board's licensing staff have assembled helpful renewal FAQs, all of which are found on the front page of the Board's website, *www.ncbop.org.*

Item 2381 – Follow the Board on Twitter

The Board has a Twitter handle, @NCBOPNews, that mirrors content posted on the Board's website. You are encouraged to follow the Board on Twitter. The Twitter feed was an especially useful means of getting information out quickly during Hurricane Florence and Tropical Storm Michael.

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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.

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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At the time of publication the Board does not have an Instagram account, which would, in any event, be overrun with pictures of the executive director's dog.

Item 2382 – Reminder: DHHS Information for Pharmacies Is on the New CSRS Platform

North Carolina DHHS, which administers the Controlled Substance Reporting System (CSRS), is migrating the CSRS to a new software platform. DHHS emailed the below information to CSRS users several weeks ago:

> Dear CSRS User,
>
> We are pleased to announce that the new CSRS is now available.
>
> **How It Affects Me:**
>
> Your existing CSRS account has automatically been transferred into the new software system.
>
> **Important:** Your username for the new system will be the email address where you received this notice.
>
> **Action Steps:**
>
> Follow the steps below to access the new CSRS website:
>
> - Go to *https://northcarolina.pmpaware.net.*
> - Click the Reset Password button on the home page. Instructions will be emailed to you for resetting your password. If the email does not appear in your inbox, please check the junk/spam folder.
> - Once you have reset your password, you will be logged in to the system.
> - If prompted, update your demographic information.
> - To request patient reports, please review the *Quick Reference Guide: Making a Patient Request.* (The full CSRS User Guide can be found under the Help section of the website.)

Note that the old website, *https://nccsrsph.hidinc.com,* is no longer available.

Item 2383 – AWAR$_X$E Prescription Drug Safety Resources

The National Association of Boards of Pharmacy® AWAR$_X$E® Prescription Drug Safety initiative, *https://nabp.pharmacy/initiatives/awarxe,* is a terrific source of information and resources for pharmacists and patients on safe medication purchase, storage, use, and disposal (including a prescription drug disposal location finder). Consider bookmarking it as an important practice resource for you or providing a link to it on your pharmacy's website for your patients.

The *North Carolina Board of Pharmacy News* is published by the North 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.

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