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News

North Carolina Board of Pharmacy

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Item 2354 – Board Announces New Online Licensing System; Register Now Through the Gateway

In an ongoing effort to increase efficiency and provide the most secure platform possible for its licensees, registrants, and permittees, the North Carolina Board of Pharmacy has transitioned to a new online licensing system. From this point forward, all renewals, new applications, forms, and updates will be submitted and managed through a single online Gateway: *https://portal.ncbop.org.* To use the new system, all licensees and registrants must create a profile.

The first step is to visit the Gateway at *https://portal.ncbop.org* and select "Register Now." You will follow the prompts to enter contact and other information through the Board's secure server to create a unique username and password.

Once registered, your username and password will grant you access to:

- Annual renewal of your pharmacist license, pharmacy or durable medical equipment (DME) permit, technician registration, or dispensing physician/physician assistant (PA)/nurse practitioner (NP) registration (beginning November 1)
- Pharmacist exam application
- Pharmacist reciprocity application
- Pharmacist reinstatement application
- Pharmacy and DME application
- Pharmacy and DME transfer of ownership and reregistration
- Technician application/technician reinstatement
- Dispensing physician and PA/NP application and reinstatement
- Name, address, and email address changes
- Pharmacist-manager/pharmacist-in-charge change application
- Technician-to-pharmacist ratio increase request
- Various pharmacy administrative forms (drug disposal form, incident report, drug disaster and loss report, etc)
- Plus many others, including pending application status.

The Gateway will be the single portal through which all aspects of licensure and registration are managed by Board staff.

Please contact Board staff if you have questions once you complete the initial registration process.

Item 2355 – Important Update for Pharmacists on the 2018 License Renewal Process

As discussed above, the Board has changed over to a new information technology system, which will be used for 2018 license renewals. To complete the online license renewal for 2018, pharmacists will **not** have to enter their continuing education (CE) course titles or numbers. Rather, pharmacists will attest that they have completed the requisite CE requirements for renewal.

It is, of course, imperative that pharmacists truthfully attest to having completed the requisite CE requirements for renewal. For more information about CE requirement changes that go into effect January 1, 2018, pharmacists are directed to this frequently asked question (FAQ) at *www.ncbop.org/faqs/Pharmacist/CEFAQChangesEff010118.pdf.*

Item 2356 – North Carolina Medicaid and North Carolina Health Choice Statement Concerning Prior Approval Requirements for Opioid Prescriptions

North Carolina is facing an opioid epidemic. Three North Carolinians die from an opioid-related overdose every day. Modifying clinical coverage policies to promote safe opioid prescribing is an essential and significant step to realize the vision of the North Carolina Opioid Action

continued on page 4

.Pharmacy Domain Signals Safety on the Web

With only 4% of websites selling prescription drugs online following United States pharmacy laws and practice standards, consumers seeking medications online are faced with the daunting task of finding a safe site. To assist consumers and those legitimate pharmacies with an online presence, NABP has streamlined its website verification programs. As of September 1, 2017, NABP is only offering the .Pharmacy Verified Websites Program and the Verified Internet Pharmacy Practice Sites® (VIPPS®) program, providing an easy choice for safety-minded consumers and pharmacies alike. The .Pharmacy Program, which was launched in 2014, enables qualified pharmacies and pharmacy-related businesses to register a web address with the .pharmacy domain. A .pharmacy domain (pronounced "dot pharmacy") is part of a website's address like ".com" or ".biz": *www.safe.pharmacy.* It enables people to identify an online pharmacy or pharmacy-related website as safe and legitimate. Since .pharmacy is a verified domain, websites are evaluated against a set of safety standards before an applicant is approved to register the domain.

In addition to showing patients that they operate a safe website, the .pharmacy domain allows pharmacies and related entities to advertise online through Google, Bing, and Yahoo! The .Pharmacy Program replaces the e-Advertiser Approval℠ and Veterinary-VIPPS® programs for those entities that are not eligible to apply for VIPPS but want to advertise with the search engines.

For more information about the .Pharmacy Program, including the application and domain name registration process and fees, visit *www.safe.pharmacy/apply.*

Quality Processes, Risk Management, and Culture: HR-Related Policies That Conflict With a Just Culture

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition *by visiting* www.ismp.org. *ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

As health care organizations move toward a "Just Culture," one of the areas potentially overlooked is human resource (HR)-related policies and procedures. Because these policies and procedures typically describe staff expectations, individual accountability, and disciplinary processes, they must be reviewed and often revised to ensure alignment with the tenets of a Just Culture. Otherwise, the journey will be long and unsuccessful if the policies are in conflict with a Just Culture.

In a Just Culture, HR-related policies and procedures regarding safety should hold all individuals equally accountable for the quality of their behavioral choices and should not focus on errors (which are not a behavioral choice), except for the expectation to report them. Policies and procedures should reflect a tone that is proactive toward risk identification, rather than reactive to errors and adverse outcomes. They should define human error as inadvertent, with a response of consoling individuals and conducting an investigation to determine how to redesign systems to prevent errors or detect them before reaching the patient. Policies and procedures should describe how to investigate a procedural violation to determine its causes and scope, and how to coach staff who have engaged in at-risk behaviors under the mistaken, but good faith, belief that the risks were insignificant or justified. For outcome-based duties related to a business code of conduct, such as arriving to work on time and wearing identification badges, policies should be clear about expectations and the actions that will be taken when they are not met. When describing reckless behavior (actions involving a conscious disregard of what an individual knows is a substantial and unjustifiable risk), remove any reference to "negligent" or "criminal" conduct as the basis for disciplinary action. Regrettably, mere human error can result in legal action (criminal negligence), but human error is never reckless behavior. Also ensure that event reporting and investigation policies and procedures support the tenets of a Just Culture.

While HR-related policies and procedures cannot guarantee that the desired actions will be realized in practice, they are a critical step for building an organizational foundation for success. Old punitive policies risk slipping back into an unjust culture. As organizations align actual practice with a Just Culture, they also need to align supporting policies and procedures.

AMA Task Force to Reduce Opioid Abuse Promotes Safe Storage, Disposal of Opioids

The American Medical Association (AMA) Task Force to Reduce Opioid Abuse released a resource document that urges physicians and other health care providers to promote safe storage and disposal of opioids and all medications. The AMA document indicates physicians and other providers need to:

- educate patients about safe use of prescription opioids;
- remind patients to store medications out of children's reach in a safe place; and
- talk to patients about the most appropriate way to dispose of expired, unwanted, and unused medications.

The AMA resource document and additional information can be found at *www.ama-assn.org/opioids-disposal.* Options for disposing of medications safely are available in the Initiatives section of the NABP website at *www.nabp.pharmacy* under AWAR$_X$E®.

CDC Guide Shows Importance of Physicians, Pharmacists Working Together

Collaborative care by at least two practitioners working together with the patient to accomplish shared goals has been shown to improve hypertension control and cholesterol management, especially when the team involves a physician or nurse and a pharmacist, notes a new guide developed by the Centers for Disease Control and Prevention (CDC) Division for Heart Disease and Stroke Prevention, in collaboration with the American Pharmacists Association and AMA. The guide,

Creating Community-Clinical Linkages Between Community Pharmacists and Physicians, discusses the importance of community-clinical linkages specific to community pharmacists and physicians and provides a framework for how community pharmacists and physicians might approach the development of a link to help patients. In addition, the guide provides examples of existing community-clinical linkages between community pharmacists and physicians and discusses common barriers to and potential solutions for creating community-clinical linkages. The guide is available at *www.cdc.gov/dhdsp/pubs/docs/ccl-pharmacy-guide.pdf.*

FIP Report Shows Value of Pharmacists' Role in Consumers' Self-Care

Support from pharmacists will assist consumers in better health maintenance and greater health system efficiency, indicates a recently released report from the International Pharmaceutical Federation (FIP). The report, *Pharmacy as a gateway to care: Helping people towards better health,* discusses the various factors involved in individual self-care and the evidence that pharmacists can increase value for those individuals through many opportunities because informed, engaged, and educated consumers will play a greater and critical role in caring for themselves. The definition of self-care this report adopts is that of the World Health Organization: "the ability of individuals, families and communities to promote health, prevent disease, and maintain health, and to cope with illness and disability with or without the support of a health care provider."

The report is available at *www.fip.org/files/fip/publications/2017-04-Pharmacy-Gateway-Care.pdf.*

FDA Restricts Use of Codeine and Tramadol Medicines in Children; Recommends Against Use in Breastfeeding Women

As of April 2017, Food and Drug Administration (FDA) is restricting the use of codeine and tramadol medicines in children. FDA is also recommending against the use of these medicines in breastfeeding mothers due to possible harm to their infants. Codeine and tramadol medicines carry serious risks, including slowed or difficult breathing and death, which appear to be a greater risk in children younger than 12 years, and should not be used in this age group. These medicines should also be limited in some older children. Single-ingredient codeine and all tramadol-containing products are FDA-approved only for use in adults.

As indicated in the FDA Drug Safety Communication available at *www.fda.gov/Drugs/DrugSafety/ucm549679.htm,* FDA is requiring several changes to the labels of all prescription medicines containing these drugs. These new actions further limit the use of these medicines beyond their 2013 restriction of codeine use in children younger than 18 years to treat pain after surgery from removal of tonsils and/or adenoids. FDA is now adding:

- A *Contraindication* to the drug labels of codeine and tramadol, alerting that codeine should not be used to treat pain or cough and tramadol should not be used to treat pain in children younger than 12 years.
- A new *Contraindication* to the tramadol label, warning against its use in children younger than 18 years to treat pain after surgery from removal of tonsils and/or adenoids.
- A new *Warning* to the drug labels of codeine and tramadol to recommend against their use in adolescents between 12 and 18 years who are obese or have conditions such as obstructive sleep apnea or severe lung disease, which may increase the risk of serious breathing problems.
- A strengthened *Warning* to mothers that breastfeeding is not recommended when taking codeine or tramadol medicines due to the risk of serious adverse reactions in breastfed infants.

FDA urges health care providers to report side effects involving codeine- and tramadol-containing medicines to the FDA MedWatch program at *www.fda.gov/safety/medwatch.*

AVMA Warns Pharmacists and Pet Owners About Xylitol Pharmaceutical Products

Pharmaceutical products containing xylitol may be dangerous and fatal to dogs, warns the American Veterinary Medical Association (AVMA). Xylitol stimulates an insulin release that can result in severe hypoglycemia and fatal liver damage. Pharmacists and pet owners need to be aware of and protect against xylitol toxicoses, indicates AVMA. FDA-approved gabapentin capsules and tablets do not contain xylitol, but the liquid form does. In addition, xylitol-containing media might be used in compounding products if the pharmacist is uninformed about not using it.

AVMA urges pharmacists to not use xylitol-containing products when compounding for canine patients and to contact the veterinarian if a prescribed product contains xylitol. The veterinarian may be unaware that this sweetener is in the product. AVMA also encourages pet owners and caretakers to verify with the pharmacist when picking up their dog's medication at a human pharmacy that the medication does not contain xylitol. Xylitol-containing peanut butter should not be used to help a dog take its medication.

For more information, visit *atwork.avma.org/2017/05/30/eliminate-xylitol-from-canine-prescriptions.*

CDC Publishes Guide to Help Pharmacists Initiate CPAs With Prescribers

CDC published a guide that provides pharmacists with information and resources to empower them to initiate collaborative practice agreements (CPAs) with collaborating prescribers. The guide, *Advancing Team-Based Care Through Collaborative Practice Agreements: A Resource and Implementation Guide for Adding Pharmacists to the Care Team,* contains a sample CPA and sample language that can be customized by pharmacists and prescribers using their specific state laws to create a CPA. The guide includes an overview of state laws, including which states currently allow CPAs. The guide is available at *www.cdc.gov/dhdsp/pubs/docs/CPA-Team-Based-Care.pdf.*

DEA Releases New Edition of Drugs of Abuse Resource Guide

Drug Enforcement Administration (DEA) released the 2017 edition of *Drugs of Abuse, A DEA Resource Guide,* which serves as a resource on the most commonly abused and misused drugs in the US. The latest edition, which is an update to the 2015 publication, describes the consequences of drug use, a drug's effects on the body and mind, overdose potential, origin, legal status, and other key facts. It also includes the most current information on new and emerging trends in drug misuse and abuse, including fentanyl, other opioids, and synthetic drugs. The 2017 edition can be found at *www.dea.gov/pr/multimedia-library/publications/drug_of_abuse.pdf.*

continued from page 1

Plan to reduce opioid deaths by 20% by 2021. On August 27, 2017, prior approval became effective for Medicaid and North Carolina Health Choice opioid prescribed analgesic doses that exceed 120 mg of morphine equivalents per day; are greater than a 14-day supply of any opioid; or are non-preferred opioid products on the North Carolina Medicaid Preferred Drug List. The North Carolina Department of Health and Human Services (DHHS) worked closely with prescribing physicians and pharmacists to develop the best approach to reduce the oversupply of prescription opioids available for diversion and misuse, promote safe opioid prescribing for patients, and encourage alternative pain management, while minimizing administrative requirements as much as possible.

As a reminder, pharmacy providers may use the 72-hour emergency supply allowed for drugs requiring prior approval. Federal law requires that this emergency supply be available to Medicaid beneficiaries for drugs requiring prior approval (Social Security Act, Section 1927, 42 United States Code 1396r-8(d)(5)(B)). Use of this emergency supply will allow access to medically necessary medications until prior approval is obtained or a revised opioid prescription not requiring prior approval is received.

Furthermore, the Comprehensive Addiction and Recovery Act of 2016 and the rules and regulations of the Board allow a North Carolina-licensed pharmacy to provide a partial fill of a Schedule II controlled substance (CS) prescription when the prescription is written and filled in compliance with federal and state law, the partial fill is requested by the patient or the prescriber, and the total quantity dispensed in all partial fills does not exceed the total quantity prescribed. The total amount of a Schedule II CS prescription may be filled no later than 30 days from the date of the prescription.

If a pharmacist receives a verbal Schedule II CS prescription pursuant to an emergency, the pharmacist may provide a partial fill, but must provide the remainder of the prescription amount within 72 hours. After 72 hours, no further dispensing on the emergency prescription is allowed. All other requirements regarding the need to receive a hard copy (or valid electronic) prescription within seven days remain. More information can be found at *www.ncbop.org/faqs/Pharmacist/faq_SchIIControlledSub.htm.*

The North Carolina DHHS appreciates the partnership of prescribing physicians and pharmacists to combat the opioid crisis in North Carolina and to keep our fellow North Carolinians safe. Opioid safety and alternative pain management provider resources are available on the Medicaid Outpatient Pharmacy website and the Community Care of North Carolina Medicaid Opioid Safety Resources website.

Item 2357 – Board Issues Guidance to Pharmacists on Implementation of the STOP Act

The North Carolina General Assembly has passed, and Governor Roy Cooper has signed into law, the Strengthen Opioid Misuse Prevention ("STOP") Act. The STOP Act is an effort to combat the opioid abuse and misuse epidemic. The STOP Act makes numerous changes to the laws governing CS prescribing, CS dispensing, and the North Carolina Controlled Substance Reporting System. Various sections of the STOP Act become effective at differing times. The following FAQ guidance sorts out those changes and timetables: *www.ncbop.org/PDF/GuidanceImplementationSTOPACTJuly2017.pdf.*

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