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North Dakota State Board of Pharmacy News

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Update to Board Contact Information

The North Dakota State Board of Pharmacy transitioned its working email to new addresses utilizing the .pharmacy domain. The email addresses containing btinet.net will be discontinued and no longer accessible at the end of the year. Please note the new contact emails below. The Board is also utilizing the website domain *www.ndboard.pharmacy,* which redirects to the Board's current website *www.nodakpharmacy.com*. Should you have any questions, feel free to use the new email addresses at any point or call the Board office at 701/328-9535.

- Mark Hardy: mhardy@ndboard.pharmacy
- Eileen Heidrich: ndboph2@ndboard.pharmacy
- Howard Anderson: ndboph@ndboard.pharmacy
- Kathy Zahn: pdmp@nd.gov or pdmp@ndboard .pharmacy

What Is a .Pharmacy Domain?

A .pharmacy domain (pronounced "dot pharmacy") is part of a website's address like ".com" or ".biz": *www.ndboard.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 being able to register the domain.

Why Is .Pharmacy Important?

Today, the vast majority of websites selling prescription drugs online are doing so illegally – many of them sell unapproved, substandard, and counterfeit medicine. The National Association of Boards of Pharmacy® (NABP®), the official registry of the .pharmacy domain, has found that 96% of the nearly 11,600 internet drug outlets it has reviewed are out of compliance with United States pharmacy laws and practice standards. Of the websites NABP has identified as Not Recommended, 87% appear to have affiliations with networks of rogue internet drug outlets and 89% do not require a valid prescription!

EPCS Forwarding and Transferring Process

The Board has received questions and requests for further clarification on the terminology of forwarding versus transferring. The Board consulted directly with Drug Enforcement Administration (DEA) and was provided guidance relative to the process of forwarding and transferring electronic prescriptions for controlled substances (EPCS) when the patient prefers to use a different pharmacy than where the original electronic prescription was sent to by the prescriber.

In communicating with DEA as well as other entities, make sure you understand that the "forwarding" of an EPCS is meant to be a secure electronic process to send a prescription from one pharmacy to another. It is important to note that currently there are no valid "forwarding" processes between pharmacy software systems. It is anticipated that in the next year, National Council for Prescription Drug Programs standards will be updated to allow for this type of transmission between pharmacies. Until such time as this process becomes implemented, there is not a legal way to transfer an **unfilled** EPCS that has been placed "on hold" or "profiled" within a pharmacy software system.

Once the original EPCS has been filled and dispensed, any remaining refills are able to be transferred directly between two licensed pharmacists **(cannot be delegated to other staff)** on a one-time basis. The original fill of the EPCS cannot be transferred from pharmacy to pharmacy, and at this time, a new prescription would need to be requested of the prescribing practitioner, when applicable.

As pharmacists acquire the forwarding ability for EPCS in the future, it appears this capability will be extended to prescriptions in Schedules II-V. The Board anticipates that this functionality will help better serve patient care situations.

Should you have any questions or need further clarification, do not hesitate to contact the Board office.

.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.*

USP Chapter <800> Hazardous Drugs—Handling in Healthcare Settings

The recent big news in the practice of pharmacy was the decision by the United States Pharmacopeial Convention to delay the implementation of United States Pharmacopeia (USP) Chapter <800> until December 2019. This delay in implementation will provide ample time for state boards and pharmacies to determine a response to this new chapter.

USP Chapter <800> will affect not only pharmacies across the state, but also health care facilities.

USP Chapter <800> provides guidance for personal handling of hazardous drugs (HDs), including the use of personal protection equipment and proper communication, training, transport, package labeling, and disposal. It also offers specifications for the building environment for handling these HDs. For many pharmacy locations that are not compounding, the USP Chapter <800> standard may not require modification of their space. However, pharmacies that do conduct HD compounding may need to make extensive changes to come into compliance with the standard.

The Board has been talking about USP Chapter <800> standards, including whether the Board is going to adopt the standard or modify existing or current Board rules to address the new standards relative to HDs. At a minimum, there are certainly improvements that can be made in our profession relative to notification and educating staff and employees about the dangers of HDs and how to correctly limit exposure.

For many health-system pharmacies, the modification of space must be completed to accommodate USP Chapter <800> standards, as it will be the enforceable standard of both The Joint Commission and Centers for Medicare and Medicaid Services accreditation. As things progress, compliance will certainly involve education and setting policies and procedures for how these HDs will be safely handled to minimize risk, according to where a drug falls on the National Institute for Occupational Safety and Health list.

The Board encourages you to take the time to educate yourself on what implementation of USP Chapter <800> will mean to your practice and practice site. Please keep the Board informed on what you feel is the appropriate path moving forward in developing an approach to ensure limited exposure to these potentially harmful substances. The Board will more than likely create a task force to assist the Board with the pros and cons of USP Chapter <800> and to determine what the right path is for our profession in response to these new standards.

As always, please feel free to contact the Board with your thoughts and suggestions on this matter or if you wish to volunteer to serve on the task force committee to study this issue.

Board Finalizes Administrative Rules on Consultation Standards

The Board finalized the administrative rules on consultation standards to fall in line with the tenets codified in North Dakota Century Code (NDCC) 43-15-31.2. The revision allows for registered technicians to complete the task of screening patients on refilled prescriptions as an option to comply with the law. The Board's compliance officers will be discussing the rules with pharmacies in North Dakota and methods for compliance. The Board will also discuss how the profession can continue to positively impact patients, especially given the increasingly complex medication regimens and the changing models of pharmaceutical care. As always, the Board welcomes the profession's feedback. Below is the final version of each rule.

61-04-13. Patient consultation requirements. Each prescription dispensed by a pharmacy serving patients in the state and each out-of-state pharmacy providing prescriptions by mail to patients in the state must provide the following in regard to consultation:

1. Provide consultation by a pharmacist or intern on each new prescription dispensed.
2. Provide consultation by a pharmacist or intern on each refill prescription dispensed. Pursuant to [North Dakota Administrative Code (NDAC)] 61-02-07.1-05, screening a patient for consultation on a refilled prescription can be completed by a registered technician.
3. Counseling can be provided to the patient or their agent.
4. For a refilled prescription, when the patient or their agent is not available at the time of dispensing, the pharmacy must supply written or electronic materials and a toll free phone number for the patient or their agent to contact the pharmacist.
5. For a new prescription being dispensed by mail to a patient, the pharmacy must provide a consultation by telephone or supply written or electronic materials and a toll free phone number for the patient or their agent to contact the pharmacist[.]
   a. A pharmacist must assess whether it is appropriate to engage the patient or their agent through a telephone conversation or if written material accompanying the prescription is appropriate.
6. This section does not apply to prescriptions for patients exempted in NDCC 43-15-31.2[.]
7. Failure to provide proper consultation under this section is considered unprofessional conduct by the pharmacy and pharmacist under NDAC 61-04-04-01(9) and is subject to disciplinary action[.]

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61-02-07.1-05. Tasks pharmacy technicians may perform.

1. Under the responsibility of the pharmacist-in-charge or designated staff pharmacist the pharmacy technician may perform any service assigned by the pharmacist-in-charge in the preparation of pharmaceuticals to be dispensed by the pharmacist to a patient except as specified in section 61-02-07.1-06.
2. The pharmacist is legally responsible for all the pharmacy technician's activities and services performed.
3. The pharmacy technician may assess a patient receiving a refilled prescription on the need of the patient or their agent to have a consult with the pharmacist or pharmacy intern about the prescription.
   a. Assessment must include a visual display of the medication[.]
   b. Asking appropriate open ended questions on the medication and their applicable health condition.
   c. Any problematic responses must prompt the pharmacist to intervene with a consultation.

Findings of August Continuing Education Audit of Licensed Pharmacists

- 56 pharmacists were randomly audited.
- 49 pharmacists were compliant per CPE Monitor®.
- Five pharmacists were compliant with additional documentation.
- Two pharmacists did not have adequate continuing education hours.
- Those not in compliance received administrative fines and/or suspensions according to NDAC rules.

The Board will be looking to conduct random audits of pharmacy technicians before the end of 2017.

The *North Dakota State Board of Pharmacy News* is published by the North Dakota State 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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