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Minnesota Board of Pharmacy News

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Disciplinary Actions

Because of space limitations, information on disciplinary actions is no longer being included in the *Minnesota Board of Pharmacy Newsletter.* A document that provides information about recent Board disciplinary actions can be found on the Minnesota Board of Pharmacy website under the "Resources/FAQs" menu item.

Pharmacy Technicians – Registration and Continuing Education Issues

Unfortunately, many pharmacy technicians seem to confuse the Board with the Pharmacy Technician Certification Board (PTCB). The Board is a state government agency that regulates the practice of pharmacy and the manufacture, compounding, distribution, and dispensing of drugs. The Board licenses pharmacists and various businesses and registers pharmacy technicians and interns. In order to work as a pharmacy technician in the state of Minnesota, an individual must be **registered** by the Board.

PTCB is a national, private sector organization that **certifies** pharmacy technicians who have met certain requirements and passed an examination. In Minnesota, an individual does **not** have to be certified by PTCB in order to work as a technician. (Many employers want their technicians to become certified, but state law does **not** require certification.) Every year, a number of technicians do not renew their Board **registration** because they mistakenly assume that renewing their PTCB **certification** is all that is required in order to continue working as a technician.

Working as a pharmacy technician without a current registration is grounds for disciplinary action against the technician, the pharmacy in which he or she works, and the pharmacist-in-charge (PIC) of the pharmacy. Consequently, it is very important for technicians to renew their registration on time every year. The date by which pharmacy technician registrations must be renewed is **December 1** of each year – **not** December 31 as many people mistakenly believe. December 31 is actually the end of the **grace period** that the Board gives for technician registration renewals. Technician registrations expire on December 31, and individuals who have not renewed their registration by that date can no longer work as technicians; **however, renewals are supposed to be completed by December 1.** Every year, individuals who wait until the first week in January to renew their registration call the Board and ask for the late fee to be waived because they are "only a couple of days late." In reality, they are more than 30 days late, so the late fee is not waived.

Many technicians also appear to be confusing the Board's requirement to complete 20 hours of continuing education (CE) every two years with the CE requirements necessary to maintain certification through PTCB. In order to be eligible for renewal of their registrations, technicians must complete 20 hours of CE during each two-year CE cycle. Technician CE cycles begin on August 1 of odd-numbered years and end on July 31 of the next odd-numbered year. So, the last CE cycle ran from August 1, 2015, through July 31, 2017. That CE cycle is the **same** for all technicians registered by the Board. On the other hand, PTCB CE cycles vary, based on the date that an individual is first certified by PTCB.

All technicians were supposed to have certified – **to the Board** – the completion of their CE for the last two-year cycle by July 31, 2017. The Board sent out emails prior to that date, giving instructions for certifying completion of CE. However, more than 3,200 technicians failed to certify the completion of their CE by that date. All of those technicians were required to send in proof of completion of CE, such as certificates of attendance. In addition, the registration status of those technicians was changed from "Active" to "Owes CE." Technicians who are in "Owes CE" status will not be able to renew their registration for 2018 until they submit proof that they have completed CE.

Each PIC of a pharmacy located within Minnesota should verify the registration status of all technicians working in their pharmacy. This can be done by visiting the Board's website at *https://mn.gov/boards/pharmacy,* clicking on the "License Verification" link, and typing in the registration number or name of the technician. Please look under "Status" and make sure that the status is "Active."

If the status of a technician is **neither** "Active" **nor** "Owes CE," have the technician call the Board office. If the status is "Active," the PIC need do nothing else. If the status is

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

"Owes CE," the PIC should ask the technician to submit copies of proof of CE participation to the Board. When submitting proof of CE participation, technicians should include their name and registration number. Once proof of CE participation is received and approved, technician registration status will be changed back to "Active" and a renewal application will be appended to the technician's record.

If technicians do not submit proof of CE participation, or if it is not approved, they will not have a renewal application appended to their record and will not be able to renew their registration. In that case, as of January 1, 2018, the individuals will not be allowed to work as pharmacy technicians.

Pharmacy Technician Training

Rules that the Board adopted in 2011 regarding registration requirements for technicians have been in full effect since January 1, 2014. One portion of that rule change requires newly registered technicians to complete training within 12 months of their initial registration. (Technicians registered prior to January 1, 2013, who have not let their registration lapse for longer than 12 months were "grandfathered" in and do not have to complete training.) This training can be completed through a Board-approved, accredited vocational/technical institution or college; a pharmacy technician training program accredited by a Board-approved national organization that accredits pharmacy technician training programs; or a pharmacy technician training program provided by a branch of the United States armed forces or Public Health Service.

Another option for training is an employer-based training program. The rule language concerning employer-based training states that (emphasis added):

> an employer-based pharmacy technician training program [is one] that includes a minimum total of 240 hours on a one-year period to include both theoretical and practical instruction. **An employer utilizing such a program *must develop* and regularly update a technician *training manual*** that must be available for board inspection upon request. **The employer *must* also *supply* a technician who completes the training program with *written evidence of completion.*** The employer-based pharmacy technician training program must include written guidelines, policies, and procedures that define the specific tasks the technician will be expected to perform.

Please note that it is no longer acceptable for an employer to rely on some sort of informal on-the-job technician training. Any technician who was first registered on or after July 1, 2013, **must** complete appropriate training within 12 months of his or her initial registration. If an employer chooses to rely on an internal training program, the employer **must** develop a comprehensive technician training manual. The training manual must meet the requirements listed in the Board's Pharmacy Technician Training Guidance, which can be found on the Board's website.

Employers must also provide a document to technicians that indicates the technician has completed employer-based training. This could be a letter or certificate, as long as it indicates that training was completed and the date on which the training was completed. The Board is starting to get complaints from technicians and pharmacies alleging that a previous employer has either not ensured that a technician has completed training or has not provided a technician with proof of completion of training. The Board can take disciplinary action against the license of the pharmacy if such complaints are substantiated.

Staff Changes

Chief Pharmacy Surveyor **Candice Fleming** recently retired after ably serving the Board and public for 19 years. Ms Fleming received a bachelor of science degree in pharmacy from North Dakota State University (NDSU). She had extensive experience in hospital pharmacy prior to accepting her position as a pharmacy surveyor. While working for the Board, she became a certified investigator/inspector through the Council on Licensure, Enforcement, and Regulation. She also completed Sterile Compounding Inspector Training. The Board and its staff wish her a long and happy retirement.

Pharmacy Surveyor **Karen Schreiner** also recently retired, after ably serving the Board and the public for 10 years. Ms Schreiner had previous experience in nuclear, specialty, and community pharmacy practice. Like Ms Fleming, Ms Schreiner received a bachelor of science degree in pharmacy from NDSU. She also became a certified investigator/inspector through the Council on Licensure, Enforcement, and Regulation and completed Sterile Compounding Inspector Training. The Board and its staff wish her a long and happy retirement.

The Board has already filled the two pharmacy surveyor vacancies, hiring **Ms Jill Phillips** and **Dr Aaron Patterson.** Ms Phillips graduated with a bachelor of science degree from NDSU. She also earned a master of public health from the University of Liverpool, a mini master of project management from St Thomas University, and a master of organizational leadership certificate from Northwestern University. She has 27 years of experience working in outpatient, oncology, veterinary, and other pharmacy settings.

Dr Patterson graduated with a doctor of pharmacy degree from Drake University. He has over 12 years of experience in home infusion pharmacy, working as a staff pharmacist for three years and a supervisor for nine. He also worked as a staff pharmacist in outpatient pharmacies for an additional half-dozen years.

The Board also hired a new office manager, **Tami Wier,** who started last month. Ms Wier most recently served as the association manager for the Joint Commission on Allied Health Personnel, where she was responsible for the administration, operations, strategic planning, budgeting, and growth for two associations. She previously served for 14 years as operations director/manager for Goodwill-Easter Seals.

The *Minnesota Board of Pharmacy News* is published by the Minnesota 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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