October 2017

Arizona State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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Board Members

Board Mission

The Arizona State Board of Pharmacy protects the health, safety, and welfare of the citizens of Arizona by regulating the practice of pharmacy and the distribution, sale, and storage of prescription medications and devices and nonprescription medications.

The Board accomplishes its mission by:

- Issuing licenses to pharmacists, pharmacy interns, and pharmacy technicians;
- Issuing permits to pharmacies, manufacturers, wholesalers, and distributors;
- Conducting compliance inspections of permitted facilities;
- Investigating complaints and adjudicating violations of applicable state and federal laws and rules; and
- Promulgating and reviewing state rules and regulations.

The Board Is Now on Facebook

Follow the Board for the latest news and updates at *https://www.facebook.com/Arizona-State-Board-of-Pharmacy-396869467321193.*

Renewal Time

The Board is in its renewal cycle. Please verify your license or permit to see if this is your year to renew. The renewal process will end October 31, 2017.

Important: The law provides no grace period. Renewals after October 31, 2017, will be subject to a renewal fee plus a penalty fee.

Please note:

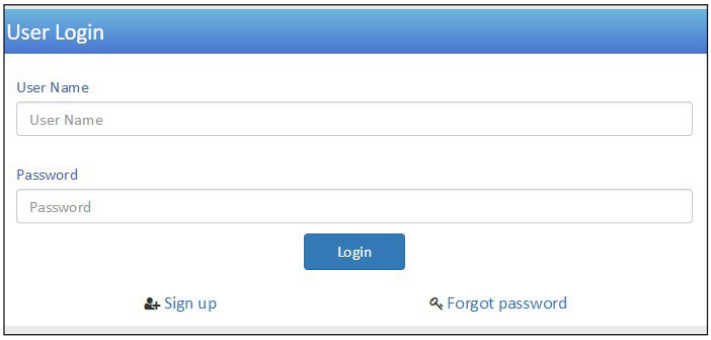
- Online renewal will be faster and convenient.
- If you mail a renewal form and fee, please **do not renew** online. All fees are nonrefundable.
- In-person renewals are not processed at the time of drop-off but in the order received.
- Renewals that are mailed or dropped off will be updated and mailed within two to three weeks depending on the volume of forms received.

Online Profiles Now Available

The online profiles are now available for all license holders and applicants (pharmacists, interns, technicians, and technician trainees). Your profile is where you can update your physical and mailing address, phone number, email address, and employment. You will also renew your license from your profile once the Board's renewal season begins in September.

If you wish to change your name, please visit *pharmacy.az.gov* and click on Resources to find the appropriate form to send to the Board, along with legal documentation of your name change and a check or money order for $10 for each copy of your license that you require.

Upon logging in to your profile, you will be greeted with the following screen:



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.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.*

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For initial registration just click the "Sign up" link at the lower left. Once you have registered, you will come to this screen and use the user name and password you created when you registered. There is also a link at the lower right to reset your password in case you forget it.

2018 Board Meeting Schedule

Date	Deadline for Requests	Deadline for Applications
January 24-25, 2018	January 5, 2018	December 29, 2017
March 28-29, 2018	March 9, 2018	March 2, 2018
May 23-24, 2018	May 4, 2018	April 27, 2018
August 1-2, 2018	July 13, 2018	July 6, 2018
September 26-27, 2018	September 7, 2018	August 31, 2018

Transferring or Forwarding an On-Hold Prescription

There has been some confusion regarding the transfer or forwarding of a prescription that has been placed "on hold." The term "on hold" refers to the situation when a pharmacy receives a new prescription and does not immediately fill it. The new prescription is normally placed in a "hold" file or entered into the pharmacy's computer system. The prescription is not filled by the pharmacy until a later date requested by the patient or mandated by the prescriber.

Some pharmacists believe that these on-hold prescriptions cannot be transferred to another pharmacy because the transfer rules only apply to refills. Drug Enforcement Administration (DEA) allows for an unfilled original electronic prescription for controlled substances (EPCS) to be forwarded from one retail pharmacy to another, including Schedule II controlled substances (CS), and there is no Arizona pharmacy law that prohibits it. Please note that this only applies to CS prescriptions and that non-CS prescriptions may be transferred in this manner.

In those instances where an on-hold EPCS is forwarded from pharmacy A to pharmacy B, pharmacy A shall transfer the prescription information to pharmacy B as required in R4-23-407(D). In the event the prescription was not previously entered into the computer, then pharmacy A should first enter the prescription into the pharmacy's computer system and assign the prescription a serial number before forwarding the prescription to pharmacy B. Pharmacy A must maintain hard copy and computer records that indicate that the original and refill prescription information were forwarded to pharmacy B and that no quantity of drug was dispensed by pharmacy A.

DEA permits the transfer of original prescription information for a prescription refill in Schedules III, IV, and V on a one-time basis. The exception to this limit requires both pharmacies to share the same database and the transfer must be processed in real time. More information will be forthcoming once clarified with DEA.

Opioid Antagonist Naloxone Now on Standing Order

As you know, we have an opioid use problem across the country. Governor Doug Ducey, having reviewed the magnitude of the problem, has declared a state of emergency in Arizona. Last year, legislation was passed to allow pharmacists to dispense the opioid antagonist naloxone without a prescription. This resulted in issues with prescription benefit managers not being able to reimburse pharmacies. During Arizona's recent legislative session, the language was revised to allow dispensing naloxone on a standing order. The Board is encouraging all pharmacists to undergo the training required to dispense this lifesaving medication.

FDA Shortage List or ASHP Shortage List?

Compounding of commercially available product is not allowed; however, when manufacturers cannot supply needed medications, compounding pharmacies and pharmacists can compound medication until the supply is once again available. Compounding pharmacies must confirm the product is on a shortage list prior to compounding.

During its August 2017 Board meeting, the Board moved to follow the Food and Drug Administration (FDA) shortage list instead of the American Society of Health-System Pharmacists' (ASHP's) shortage list. The Board is currently working on drafting a substantive policy, to be posted on the Board website. Information about drug shortages is available on FDA's website at *https://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050796.htm#q4*.

Disciplinary Actions and Updates

Pharmacy Technician

Veronica SantaMaria (T057156) – Denial of pharmacy technician trainee license.

Pharmacists

Mark Forster (S009865) – Respondent's license was surrendered and a civil penalty in the amount of $3,000.

Thomas Goebig, PharmD (S013463) – Respondent's license to practice pharmacy in the state of Arizona is revoked.

Stefan Reiner, PharmD (S020797) – Respondent's license is on probation for five years subject to the terms and conditions of joining Pharmacists Assisting Pharmacists of Arizona and being in good standing with the program.

Ralph Troller (S020355) – Respondent's license to practice pharmacy in the state of Arizona has been revoked.

Permit

Synergy Rx Pharmacy (Y005973) – Respondent's permit as a nonresident pharmacy is surrendered and a civil penalty in the amount of $100,000.

Disciplinary Actions and Updates – Other Health Boards

Arizona Medical Board

Philip J. Berent, MD #45421 – Summary suspension effective June 23, 2017. Respondent's license to practice allopathic medicine in the state of Arizona is summarily suspended. Respondent is prohibited from practicing medicine in the state of Arizona and is prohibited from prescribing any form of treatment including prescription medications or injections of any kind.

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Celia R. Elias, MD #26173 – Interim practice restriction. Respondent is prohibited from prescribing CS in the state of Arizona pending the outcome of a formal interview or formal hearing.

Gregory L. Ellison, MD #12426 – Interim practice restriction. Respondent is prohibited from engaging in the practice of medicine in the state of Arizona as set forth in Arizona Revised Statutes (A.R.S.) §32-1401(22) until respondent applies to the Board and receives permission to do so.

Steve Fanto, MD #21415 – Interim practice restriction. Respondent is prohibited from engaging in the practice of medicine in the state of Arizona as set forth in A.R.S. §32-1401(22) until he applies to the executive director and receives permission to do so.

Norm M. Fernando, MD #15894 – Interim practice restriction. Respondent is prohibited from engaging in the practice of medicine in the state of Arizona as set forth in A.R.S. §32-1401(22) until he applies to the executive director and receives permission to do so.

Kenneth M. Fisher, MD # 12762 – Decree of censure. Respondent is placed on probation for a period of five years. Respondent's practice is restricted in that he shall not prescribe CS in the state of Arizona during the period of this probation.

Paresh Goel, MD #44344 – Interim practice restriction. Respondent is prohibited from engaging in the practice of medicine in the state of Arizona as set forth in A.R.S. §32-1401(22) until he applies to the executive director and receives permission to do so as stated in paragraph 15 under the interim order.

Brett D. Goettsch, MD #24235 – Interim practice restriction. Respondent is prohibited from engaging in the practice of medicine in the state of Arizona as set forth in A.R.S. §32-1401(22) until he applies to the executive director and receives permission to do so.

Marshall W. Jones, MD #4192 – Surrender of medical license effective August 24, 2017.

Michael S. Kuntzelman, MD #13565 – Interim practice restriction. Respondent is prohibited from prescribing CS in the state of Arizona until completion of continuing medical education (CME). After completion of CME, respondent shall be permitted to prescribe buprenorphine, only for treatment of addiction and only at generally accepted doses.

Jan John Liszka-Hackzell, MD #27923 – Surrender of medical license effective August 3, 2017.

Brian E. McCarthy, MD #40004 – Summary suspension effective August 2, 2017. Respondent's license to practice allopathic medicine in the state of Arizona is summarily suspended. Respondent is prohibited from practicing medicine in the state of Arizona and is prohibited from prescribing any form of treatment, including prescription medications or injections of any kind.

Alpen Bhaktikumar Patel, MD #47525 – Interim practice restriction. Respondent is prohibited from engaging in the practice of medicine in the state of Arizona as set forth in A.R.S. §32-1401(22) until he applies to the executive director and receives permission to do so as stated in paragraph 3 under interim order. Respondent may not request release from or modification of this Interim Consent Agreement for Practice Restriction until he has been re-evaluated, including a medical polygraph examination, and any recommended treatment is completed.

Phillip L. Saunders, MD #27714 – Interim practice restriction. Respondent is prohibited from engaging in the practice of medicine in the state of Arizona as set forth in A.R.S. §32-1401(22) until he applies to the executive director and receives permission to do so.

Frederic B. Wilson, MD #44684 – Motion for rehearing/review denied. Revocation effective August 7, 2017.

Arizona Regulatory Board of Physician Assistants

Sean W. Smith, PA #5082 – Interim practice limitation (non-disciplinary). Respondent is prohibited from engaging in the practice of medicine under physician supervision in the state of Arizona as set forth in A.R.S. §32-2501(13) until he applies to the Board and receives permission to do so as stated in paragraph 2 under interim order.

The *Arizona State Board of Pharmacy News* is published by the Arizona 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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