January 2018

News

# Arizona State Board of Pharmacy

*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*.

## Technology-Assisted Verification: R4-23-1104 and R4-23-1104.01

*By Tom Van Hassel, Board President*

Arizona has joined a growing number of states to approve the prescription medication verification process utilizing technology advances. The duties of pharmacy technicians have a new permissible role in the prescription dispensing process, the effective date of which will be posted on the Board's website upon publication by the Arizona Secretary of State. Certified technicians may now perform a final technology-assisted verification of the product in a prescription to be dispensed. This is a change in the product selection process and does not include items of professional practice that are reserved for the pharmacist or pharmacy intern. If a pharmacy chooses to implement this process change, the pharmacist-in-charge (PIC) or permittee holder shall develop and implement the procedures necessary to ensure accuracy and shall promote following those procedures. These policies must specify the allowed duties a technician may perform to ensure compliance with the rule. These policies must also include the training requirements, monitoring, and evaluation process to be used to ensure competency of the verification system utilized. To be eligible, a technician must have a minimum of 1,000 hours of technician work experience and must complete four hours of continuing education (CE) prior to training and biannually thereafter on patient safety. The products that may be checked via this procedure must have a manufacturer's or robotically applied barcode for a unit-dose product. Compounded items or Schedule II controlled substances (CS) may not be verified by this manner and require final product verification by the pharmacist or intern. Further questions are answered and additional details are available at the Board office.

## Pharmacy Technicians Working for Practitioners

Being licensed as a pharmacy technician trainee or pharmacy technician allows you to work under the supervision of a pharmacist. Over the past year, the Board office has received many calls asking if a pharmacy technician trainee or pharmacy technician can work for a medical practitioner. Though the individual can work for whomever he or she chooses, he or she cannot use the title "pharmacy technician trainee" or "pharmacy technician" unless he or she is under direct supervision of a pharmacist.

# National Pharmacy Compliance News

***January 2018***

NABPF
National Association of Boards of Pharmacy Foundation

The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.


## *FDA Draft Guidance Addresses Delayed Enforcement of DSCSA Requirements for Product Identifiers*

Food and Drug Administration (FDA) issued a draft guidance for industry that informs manufacturers and other supply chain stakeholders that although manufacturers are to begin including a product identifier on prescription drug packages and cases on November 27, 2017, FDA is delaying enforcement of those requirements until November 2018 to provide manufacturers additional time and avoid supply disruptions. The compliance policy outlined in the June 2017 draft guidance, *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy,* applies solely to products without a product identifier that are introduced into commerce by a manufacturer between November 27, 2017, and November 26, 2018. While manufacturers work to meet product identifier requirements, they must comply with other Drug Supply Chain Security Act (DSCSA) requirements. The draft guidance can be accessed from FDA's website at *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm565358.htm.*

## *Amount of Prescribed Opioids Remains High, Reports CDC*

The amount of opioids prescribed remains approximately three times as high as in 1999, despite reductions in each year after 2010 through 2015. Centers for Disease Control and Prevention (CDC) researchers analyzed retail prescription data to assess opioid prescribing in the United States from 2006 to 2015 and county-level prescribing patterns in 2010 and 2015. According to a CDC report, results of the study showed higher amounts of opioids were prescribed in counties that had a greater percentage of non-Hispanic white residents, a higher prevalence of diabetes and arthritis, micropolitan status (ie, town/city; nonmetro), and higher unemployment and Medicaid enrollment rates. The researchers conclude that health care providers should carefully weigh the benefits and risks when prescribing opioids outside of end-of-life care, follow evidence-based guidelines (eg, CDC's *Guideline for Prescribing Opioids for Chronic Pain*), and consider non-opioid therapy for chronic pain treatment.

Additionally, the researchers conclude that state and local jurisdictions can use these findings along with prescription drug monitoring program (PDMP) data to identify prescribing patterns that place patients at risk for opioid use disorder and overdose and to target interventions with prescribers based on opioid prescribing guidelines. The July 7, 2017 *Morbidity and Mortality Weekly Report,* "Vital Signs: Changes in Opioid Prescribing in the United States, 2006–2015," can be accessed on the CDC website at *www.cdc.gov/mmwr/index.html* in the Weekly Report section.

## *AMA Opioid Task Force Encourages Co-Prescribing Naloxone to At-Risk Patients*

The American Medical Association (AMA) Opioid Task Force encourages physicians to consider co-prescribing naloxone when it is clinically appropriate to do so. The AMA Opioid Task Force offers several questions for determining whether to co-prescribe naloxone to a patient or a patient's family member or close friend, which may be found in the August 2017 document, "AMA Opioid Task Force naloxone recommendations," available on the AMA opioid microsite at *https://www.end-opioid-epidemic.org.*

The Naloxone section of the AMA opioid microsite also offers physicians multiple resources on co-prescribing naloxone in their practice and community. To help end the opioid epidemic, the AMA Opioid Task Force made several recommendations for physicians, including registering and using state PDMPs, training and education on evidence-based treatment, and promoting safe storage and disposal of opioids and medications.

## *Opioid Addiction Medications Should Not Be Withheld From Patients Taking Benzodiazepines or CNS Depressants*

Opioid addiction medications – buprenorphine and methadone – should not be withheld from patients taking benzodiazepines or other drugs that depress the central nervous system (CNS), advises FDA. The combined use of these drugs increases the risk of serious side effects; however, the harm caused by untreated opioid addiction usually outweighs these risks. Careful medication management by health care providers can reduce these risks, notes a safety alert. FDA is requiring this information to be added to the buprenorphine and methadone drug labels along with detailed recommendations for

minimizing the use of medication-assisted treatment drugs and benzodiazepines together.

Health care providers should take several actions and precautions and should develop a treatment plan when buprenorphine or methadone is used in combination with benzodiazepines or other CNS depressants. Additional information may be found in an FDA Drug Safety Communication announcement at *www.fda.gov/Drugs/DrugSafety/ucm575307.htm.*

## New Study Shows Substantial Variation in the Availability of Pharmacies Across the Country

Despite the rising number of US pharmacies from 2007 to 2015, the availability of pharmacies varied significantly across local areas, indicates a new study. The study, *The availability of pharmacies in the United States: 2007–2015,* found that the number of community pharmacies increased 6.3% from 63,752 to 67,753 between 2007 and 2015. Although the number of pharmacies per capita remained at 2.11 per 10,000 individuals between 2007 and 2015, the researchers found substantial variation across counties. "Some counties have 13 pharmacies per capita, while others have none," said Dima Qato, lead study author and assistant professor of pharmacy systems, outcomes and policy, in a University of Illinois at Chicago (UIC) news release.

In 2015, counties in the highest quintile had nearly three-fold more pharmacies than those in the lowest quintile. Counties in the lowest quintile are located in the Pacific West, Southwest, and Great Lakes regions, while counties with the highest tend to be located in the Northeast, Southeast, Northern Appalachia, and Plains states. The researchers conclude that future programs and policies should address the availability of pharmacies and ensure that pharmacy characteristics, including accommodations such as multilingual staffing and home delivery, align with local population needs.

To view the study, visit *https://doi.org/10.1371/journal.pone.0183172.* The UIC news release is available at *https://today.uic.edu/access-to-pharmacies-limited-to-some-patients.*

## Consent Decree Entered Against Outsourcing Facility Isomeric Pharmacy Solutions

Under a consent decree of permanent injunction entered in August 2017, Isomeric Pharmacy Solutions of Salt Lake City, UT, its owners, and chief operating officer are prohibited from manufacturing, processing, packing, holding, or distributing drugs until they comply with the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its regulations, in addition to other requirements. Isomeric manufactured and distributed purportedly sterile drug products, including injectable and ophthalmic drugs, that were adulterated because the drugs were made under insanitary conditions and in violation of current good manufacturing practice requirements under the FD&C Act, according to the complaint for permanent injunction. The complaint also alleges that Isomeric manufactured and distributed unapproved drugs and drugs that were misbranded because their labeling did not bear adequate directions for use. Isomeric initially registered as an outsourcing facility in July 2015 and reregistered in December 2015 and January 2017. Additional information is available in an FDA news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm570130.htm.*

## FDA Issues Warning on Alcohol Pads or Benzalkonium Chloride Antiseptic Towelettes Made by Foshan

In September 2017, FDA alerted health care providers and patients to not use alcohol pads or benzalkonium chloride antiseptic towelettes made by Foshan Flying Medical Products Co, Ltd, located in China, due to lack of sterility assurance and other quality issues. These products are distributed by Total Resources International, of Walnut, CA, and Simple Diagnostics, Inc, of Williston Park, NY. The use of these alcohol pads and antiseptic towelettes could cause infections.

FDA placed all drug products made by Foshan on import alert on May 23, 2017, to stop these products from entering the US. However, FDA is concerned these products might still be in distribution in the US. FDA also sent Foshan a warning letter on August 1, 2017, for violations of current good manufacturing practice regulations. FDA initially contacted Foshan regarding a recall on May 25, 2017, and had several follow-up meetings with the company. Foshan has not taken action to remove its alcohol pads or antiseptic towelettes from the market. The safety alert posted to FDA's website may be found at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm574576.htm.*

Pharmacies and health care facilities that have alcohol pads and antiseptic towelettes labeled by Total Resources or Simple Diagnostics should immediately stop using them and discard the products. Adverse events or side effects related to the use of these products may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/MedWatch/report.*

## Online Profiles

Since implementing the online profile system for licensees, the Board has had a lot of activity that will result in more accurate contact and employment information in the database. This will allow the Board to be better engaged with its license holders. The Board will continue to upgrade its profile database to not only improve Board communication, but also capture all the different specialties out there. Today, it is difficult for the Board to tell how many pharmacists are hospital-oriented versus retail-oriented.

**Coming soon:** Online profiles for permit holders. Within the next month, you will be able to create a profile for your business. The hope is to allow business owners to update their PIC/designated representative and mailing address.

For the latest news and updates to the Board, please sign up and connect with the Board on Facebook.

## AHCCCS

As we dive deeper and further dissect data to help understand the opioid epidemic, it has been noticed that many patients are paying cash and allowed to circumvent the insurance process. Please note that when pharmacies participate with insurance payors, they are committed to the provider participation agreement.

As stated in the Arizona Health Care Cost Containment System (AHCCCS) Provider Participation Agreement:

> 8. The Provider shall comply with all AHCCCS and/or Contractor Provider Manuals and Policy Guidelines, including the AHCCCS Minimum Subcontract Provisions available at the AHCCCS public web site, and any amendments thereto, all of which are incorporated by reference into this Agreement. The provider has an affirmative obligation to routinely check the AHCCCS website for any revisions or new information and to ensure compliance.

**In essence,** the Board expects pharmacy providers to explicitly follow the AHCCCS Medical Policy Manual, particularly Chapter 310-V on pharmacy services, which outlines opioid limitations. We all need to work together on the opioid crisis initiatives, and members should not be circumventing the system by offering to pay cash and the pharmacy should not circumvent the system by accepting cash.

The AHCCCS Provider Participation Agreement is available at *https://www.azahcccs.gov/PlansProviders/Downloads/ProviderRegistration/ProviderPartAgreementForm.pdf.*

There are also two companion documents available with regard to opioid limitations:

- Exhibit 310-V-2 7-Day Supply Limit of Prescription Opioid Medications Exclusions Specifications: This document explains the process for prescribing clinicians to request an exception to the policy and also provides directions to the pharmacy for obtaining the exception from the pharmacy benefits manager.
- Exhibit 310-V-3, ICD-10-CM Diagnosis Code Description: This document provides the authorized ICD-10 diagnostic codes when requesting an exception for traumatic injuries.

## State of Emergency – Opioid Epidemic

Several months ago, Governor Doug Ducey declared a state of emergency on opioid misuse. This created a heightened awareness and tasked agencies to make recommendations on how we all can face this challenge together. As a result, below are the recommendations being proposed.

**RECOMMENDATION BRIEF: OPIOID LEGISLATION**

**Proposal**: Submit a legislative package to comprehensively address the identified problems through the following legislative solutions (bolded solutions are considered high impact):

| Category | Problem | Legislative Solution |
|---|---|---|
| Prescribing Requirements | Arizonans are being prescribed too many pills | **Impose a 5 day limit on all first fills for opioid naïve patients for all payers** |
| | Arizonans are being prescribed high doses of opioids | Require a limit (and tapering down) of doses to less than 90 MME. (Taper down would occur over years, exemptions for specific situations would be made in statute) |
| | Paper prescriptions are easily forged, leading to fraudulent prescriptions | Require e-prescribing for Schedule II controlled substance medications |
| Promote Safe Prescribing and Dispensing | Arizonans may not understand the dangers of opioids | **Require different labeling and packaging for opioids ("red caps")** |
| | Private physicians can dispense opioids with little oversight | Eliminate dispensing of controlled substances by prescribers |
| | Pharmacists do not have to check the CSPMP prior to dispensing | Require pharmacists to check the CSPMP prior to dispensing an opioid or benzodiazepine |
| | Clinicians lack adequate education on the dangers of opioid prescribing and pain management options | Require at least 3 hours of opioid-related CME for all professions that prescribe/dispense opioids |
| | Arizona can't adequately analyze opioid/substance abuse treatment data from payers due to lack of transparency | Establish an all payers claim database |
| | There are no specific regulations for pain management clinics | **Regulate pain management clinics to prohibit "pill mill" activities** |
| | Prescribers are exempted from checking the CSPMP if they write a prescription for 10 days or less. | Change exemption to match the 5 day fill limit; exempt for prescriptions of 5 days or less. |
| | Law enforcement agencies have difficulty enforcing illegal prescribing or dispensing | Change law enforcement authority to ensure clear enforcement capabilities |
| | Hospice providers cannot properly dispose of unused opioids of former patients | Establish authority for hospice providers to properly dispose of opioids to prevent diversion |
| Decrease the Risk of Opioid Use Disorder | Alternative pain treatments are not being considered and referrals to substance abuse treatment services take too long; opioids are faster to prescribe | Eliminate or decrease the amount of time a prior authorization can take |
| | Pill mills and opioid dispensing are not highly regulated | Establish enforcement mechanisms for pill mills and illegal opioid dispensing |
| Improve Access to Treatment | Too many Arizonans are not receiving timely medical care for overdose for fear of prosecution | **Enact a good Samaritan law to allow bystanders to call 911 for a potential opioid overdose** |
| | Continuity of care for individuals receiving MAT treatment is not fluid | Require licensed behavioral health residential facilities and recovery homes to develop policies and procedures that allow individuals on MAT to continue to receive care in their facilities |

## Disciplinary Actions and Updates

### Pharmacy Technicians

**Valerie Jimenez (T014727)** – Respondent's license as a pharmacy technician is surrendered.

**Sandra Kay Long, Pharmacy Technician Trainee (T055430)** – Respondent's license as a pharmacy technician trainee is surrendered.

**Rocko Reynaldo Herrera, Pharmacy Technician Applicant** – Upon execution of this consent agreement, applicant shall immediately contact Treatment Assessment

*Continued on page 5*

*Continued from page 4*

Screening Center and arrange to participate in a random drug screening program for a minimum of 12 months.

### Pharmacists

**Lindsey Dalzell-Thai (S013641) –** Probation for a minimum of five years beginning October 6, 2016. A contract with Pharmacists Assisting Pharmacists of Arizona (PAPA). Respondent shall furnish all pharmacy employers with a copy of the amended consent agreement.

**Dorian Foster (S021101) –** Suspension for six months beginning July 19, 2017. Probation in effect after approval of suspension to be lifted. Respondent shall enter into a contract with PAPA. Respondent shall furnish all pharmacy employers with a copy of the consent agreement.

**Ronald Jasensky (S008473) –** Civil penalty of $2,000, complete six hours of CE in veterinary pharmacy.

**Eric McCarthy (S018296) –** Respondent shall enter into a contract with PAPA. Probation for four years and three months. Respondent shall furnish all pharmacy employers with a copy of the Board order throughout the term of his probation.

**Michael Ira Smith (S013524) –** Interim order. Respondent's license as a pharmacist is suspended.

### Interns

**Matthew Crowley (I011701) –** Suspension for six months. Probation in effect after approval of suspension to be lifted. Respondent shall enter into a contract with PAPA. Respondent shall furnish all pharmacy employers with a copy of the Board order throughout the term of his probation.

**Jamie Hudgens (I012090) –** Sign new contract with PAPA, which shall extend for the entire term of the five-year probation. Respondent shall furnish all pharmacy employers with a copy of the consent agreement.

## *Disciplinary Actions and Updates – Other Health Boards*

### Arizona Medical Board

**Stephen A. Bass, MD #41904 –** Request for inactive with cause and order inactivating license with cause. Physician shall not practice medicine in the state of Arizona or any other state, territory, or district of the United States or a foreign country while license is inactive.

**William B. Dabney, MD #5796 –** Interim practice restriction. Respondent is prohibited from engaging in the practice of medicine in the state of Arizona as set forth in Arizona Revised Statute (A.R.S.) §32-1401(22) until he applies to the executive director and receives permission to do so.

**Michael S. Kuntzelman, MD #13565 –** Letter of reprimand and probation with practice restriction. Respondent placed on five-year probation. Respondent's practice is restricted in that the respondent shall not prescribe CS in the state of Arizona, except respondent may prescribe Suboxone® or buprenorphine for the purposes of addiction treatment.

**Edward B. Nash, MD #15841 –** Practice limitation. Physician's practice is limited in that he shall not practice medicine in the state of Arizona and is prohibited from prescribing any form of treatment including prescription medications until physician applies to the Board and receives permission to do so.

**Ellen T. Olson, MD #40418 –** Interim practice restriction. Respondent is prohibited from engaging in the practice of medicine in the state of Arizona until she applies to the executive director and receives permission to do so. Respondent shall undergo an assessment with the Board's Physician Health Program contractor and comply with any and all recommendations that arise as a result of the assessment.

**Ronald E. Parfitt, MD #20680 –** Interim practice restriction. Respondent is prohibited from prescribing CS in the state of Arizona pending the outcome of a formal interview or formal hearing in this matter.

**Mari E. Schenk, MD #25685** – 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 respondent applies to the executive director and receives permission to do so.

**Gary N. Spirtos, MD #26761 –** 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.

**Patricia S. Sullivan, MD #40062 –** Decree of censure with probation and practice restriction. Respondent shall not prescribe CS in the state of Arizona in any setting for the duration of probation. Effective October 4, 2017.

**Luis S. Tan, MD #3848 –** Practice limitation (non-disciplinary). Physician 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 Board and receives its affirmative permission to do so.



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