



Arizona State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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- Dennis McAllister, RPh Member
- Reuben Minkus Member (Public)
- Doug Skvarla, RPhMember
- Kristen Snair, CPhTMember (Technician)

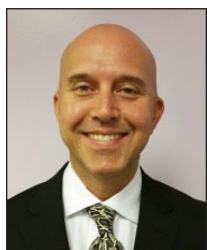
Board Mission

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.

Board Member Appointment



Doug Skvarla is extremely excited to become the newest member of the Board. Doug has been a licensed pharmacist in Arizona for 21 years, working 18 years in retail and three years in mail-order pharmacy. Doug was born and raised in Pittsburgh, PA, where he attended Duquesne University Mylan School of Pharmacy. Doug is married to his beautiful wife, Courtney, who also happens to be a pharmacist. During his free time he loves to go fishing, ride bikes, exercise, and visit friends over dinner. Doug states, "Over the last two decades, I have seen the profession of pharmacy change in so many ways. Coming out of school, I would have never guessed that as pharmacists we would be making differences in patients' lives through immunizations and medication therapy management. The profession will continue

to evolve and I am very excited to advance the profession while ensuring public safety to our communities."

New CSPMP Director



Elizabeth Dodge, PharmD, is the new director of the Controlled Substances Prescription Monitoring Program (CSPMP). She is a native of Montana and graduated from the University of Montana in 2002. Elizabeth began her career working both in the hospital and retail setting. In 2005 she pursued a desire to try something new, which meant leaving Montana and moving to Reno, NV. She has lived in Reno for the past 11 years. She enjoys running, camping, and being outdoors with her husband and three dogs.

License/Permit Renewal

On September 2, 2016, the Board began accepting renewal applications for licenses and permits expiring on October 31, 2016. If your license or permit expires on October 31, 2016, you will be able to renew online, through the mail, or at the Board office. If you wish to pay by credit or debit card, you must apply online. The Board does not accept credit or debit card payments in the office. If you apply through the mail or in person, you must submit a check or money order made payable to the Arizona State Board of Pharmacy with your completed renewal application.

After October 31, 2016, all licenses/permits that are not renewed will be deemed late and subject to a late penalty fee of 50% of the renewal fee.

Just a reminder: If you are a nonresident pharmacy permit holder, the Board does not require you to have an Arizona-licensed pharmacist as your pharmacist-in-charge.

Permit or Certificate Verification

All permit and certificate verification required for other jurisdictions (domestic or international) will be subject to a \$15 fee.

Certificate of Free Sale and Good Manufacturing Practice Certificate

Purpose: The vitamin supplement industry is a **multi-billion-dollar** business. The Board wants to create an opportunity for businesses to come to Arizona and be able to manufacture and distribute product/merchandise to ultimately create a more viable state.


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National Vaccine Safety Surveillance Program Available for Reporting Adverse Events

The Vaccine Adverse Event Reporting System (VAERS) eSubmitter program, a national vaccine safety surveillance program cosponsored by the Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA), is available for the reporting of any clinically significant adverse event that occurs after the administration of any vaccine licensed in the United States. VAERS information is analyzed by CDC and FDA to identify new safety concerns. VAERS reports can be filed by anyone, including health care providers, manufacturers, state immunization programs, and vaccine recipients. Vaccine recipients are encouraged to seek help from their health care provider when filling out the VAERS form. Health care providers can find information about submitting a report on the VAERS website at <https://vaers.hhs.gov/professionals/index>.

Improper and Unsafe Vaccine Storage

 *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.*

Few issues are more important than proper storage and handling of vaccines, because their ability to prevent disease is dependent on these factors. To maintain stability, most vaccines must be stored in a refrigerator or freezer, and many also require protection from light. Excessive heat or cold – even a single exposure in some instances – can reduce vaccine potency. These temperature excursions are often due to improper refrigeration or freezer units, inadequate thermostat controls, and refrigeration/freezer units with inadequate space to allow good air circulation and even temperatures.

Improper and unsafe storage can also result in serious errors caused by selecting the wrong vaccines, diluents, and other medications with look-alike names and/or labeling and packaging. Storing vaccines close to each other has led to dispensing and administering the wrong vaccine or wrong form of vaccine (eg, adult versus pediatric). Storing vaccines too close to non-biologic medications in a refrigerator or freezer has also led to serious adverse outcomes, particularly when the mix-up

involved a vaccine and a high-alert medication. For example, vials of insulin have frequently been mistaken as influenza vaccine, and various neuromuscular blocking agents have been used to reconstitute vaccines or were mistaken as influenza or hepatitis B vaccines.

Store vaccines in their own dedicated refrigeration and freezer units. Regular temperature monitoring is necessary, and technology is available to assist with alarmed, continuous monitoring devices that can alert staff via email and pager if a unit is out of specified range. Separate vaccine vials and syringes into bins or other containers according to vaccine type and formulation, keeping diluents with the appropriate vaccines. Never store different vaccines in the same containers. Do not store vaccines with similar labels, names, abbreviations, or overlapping components immediately next to each other or on the same shelf. Separate the storage areas of pediatric and adult formulations of vaccines. Label the specific locations where vaccines are stored to facilitate correct age-specific selection and to remind staff to combine the contents of vials. ISMP's March 26, 2015 newsletter¹ contains additional strategies, as does a Vaccine Storage & Handling Toolkit available from CDC.²

References

1. ISMP. Recommendations for practitioners to prevent vaccine errors. Part 2: analysis of ISMP vaccine errors reporting program (VERP). *ISMP Medication Safety Alert!* 2015;20(6):1-6.
2. CDC. Vaccine storage & handling toolkit. www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf. June 2016.

Coalition Reports Impact of Educational Efforts on Safe Acetaminophen Use

The Acetaminophen Awareness Coalition reports that progress has been made to increase consumer awareness about the safe use of acetaminophen. The coalition also notes a decline in unintentional overdoses. The National Poison Data System's 2015 report indicates unintentional acetaminophen exposures, including dosing errors and accidental misuse, have decreased through 2013 after a peak in 2009. In addition, a nationwide survey indicates the number of consumers who understand that exceeding the recommended daily dose of acetaminophen may lead to liver damage has increased to 87% in 2013 from 78% in 2010. The survey also reports the number of consumers who think it is important to check the medicine label for the maximum daily dose increased to 98% in 2013 from 93% in 2010.

Developed in 2011, the Know Your Dose campaign encourages pharmacists and other health care providers to talk to their patients about medicine safety and acetaminophen use. The Know Your Dose campaign offers a list of helpful health tips to share with patients, including the following:

- (1) Read and follow the label.
- (2) Know which medicines contain acetaminophen.



- (3) Take only one medicine at a time that contains acetaminophen.
- (4) Ask a health care provider or pharmacist about dosing instructions or medicines that contain acetaminophen.

Pharmacists may download or order free educational materials, including posters, flyers, and talking points, to give their patients on the Know Your Dose website, www.knowyourdose.org.

FDA Offers Webinars on Online Drug Information Resources for Students and Clinicians

FDA's Division of Drug Information in the Center for Drug Evaluation and Research presents a series of CE webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Previous webinar topics have included an overview of FDA's expanded access program and the pregnancy and lactation labeling rule. The webinars and presentation slides can be accessed on FDA's website at www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm.

Fresenius Kabi Recalls Sensorcaine-MPF (Bupivacaine HCl) Injection, USP

In April 2016, Fresenius Kabi USA recalled a single lot of Sensorcaine®-MPF (bupivacaine HCl) injection, USP, 0.75%, 7.5 mg/mL, 30 mL fill in a 30 mL vial, because of visible particulate matter characterized as glass observed by the company during inspection of reserve samples. The recalled product was shipped in the US to wholesaler and distributor outlets between March 4, 2016, and March 21, 2016, and has an expiration date of September 2019. The recall affects lot number 6111504, product code 470237, and National Drug Code number 63323-472-37. The product is supplied as 0.75% strength in a 30 mL single-dose flint molded vial and is packaged in units of 25. To date, Fresenius Kabi has not received any reports of adverse events regarding this recall, indicates the press release posted to the FDA website.

Health care facilities that have the affected lot are instructed to immediately discontinue distributing, dispensing, or using the lot and return all units to Fresenius Kabi. Distributors are instructed to immediately notify their customers who have been shipped or may have been shipped the recalled product. Adverse reactions or quality problems may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting program at www.fda.gov/MedWatch. Additional details are available on FDA's website at www.fda.gov/Safety/Recalls/ucm497812.htm.

Oral Liquid Docusate Sodium by PharmaTech Recalled Due to Contamination

In July 2016, FDA alerted health care providers that PharmaTech, LLC, of Davie, FL, voluntarily recalled all non-expired lots of Diocto Liquid, a docusate sodium solution

distributed by Rugby Laboratories of Livonia, MI. The affected product was distributed nationwide in one-pint (473 mL) bottles with a Rugby label. FDA confirmed the product has been contaminated with *Burkholderia cepacia*, a bacteria linked to an outbreak in five states. The safety alert indicates FDA has received several adverse event reports of *B. cepacia* infections in patients, and some of these reports identify liquid docusate sodium products manufactured by companies other than PharmaTech. FDA and CDC continue to investigate the extent of this issue in order to identify other potentially contaminated liquid docusate sodium products. FDA joins CDC in recommending that clinicians not use any liquid docusate sodium product as a stool softener or for any other medical purpose. Adverse events or side effects may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at www.fda.gov/MedWatch. More information may be found in the safety alert on FDA's website at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm511528.htm.

NABP Seeks Pharmacists From Districts 1, 5, and 7 to Serve as Volunteer Item Writers

The National Association of Boards of Pharmacy® (NABP®) is seeking pharmacists who reside in states in the following districts to serve as volunteer item writers:

- ◆ **District 1:** Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont.
- ◆ **District 5:** Iowa, Minnesota, Nebraska, North Dakota, and South Dakota.
- ◆ **District 7:** Alaska, Idaho, Montana, Oregon, Washington, and Wyoming.

In an effort to secure more individuals representative of these areas of the country, NABP encourages pharmacists in all areas of practice as well as school and college of pharmacy faculty who reside in these states to apply.

NABP uses volunteer item writers to develop questions for the following examination programs: North American Pharmacist Licensure Examination® (NAPLEX®), Multistate Pharmacy Jurisprudence Examination® (MPJE®), Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®), Pharmacy Curriculum Outcomes Assessment® (PCOA®), and Pharmacist Assessment for Remediation Evaluation® (PARE®).

Interested individuals should complete the online interest form available in the Meetings section of the NABP website. Individuals who are selected will receive further information on opportunities to attend and participate in NABP-hosted workshops.

For more information about NABP item writing, visit the Meetings section of the NABP website at www.nabp.pharmacy, or contact CompAssess@nabp.pharmacy.

Description: The **certificate of free sale** is evidence that goods, ie, nutraceuticals, are legally sold or distributed in the open market, freely without restriction, and approved by the regulatory authorities in the country of origin (United States).

The **Good Manufacturing Practice (GMP) certificate** validates a system in place to ensure that products are consistently produced and controlled according to quality standards and covering all aspects of design, monitoring, and control of manufacturing processes and facilities to ensure that products do not pose any risk to the consumer or public. This would include, but is not limited to, a positive GMP inspection according to Title 21 Code of Federal Regulations Parts 210-211.

Effective immediately, the Board has expanded its role in providing these certificates.

Fingerprint Clearance Cards

The Board no longer accepts fingerprint cards. If you are applying for licensure as a pharmacy technician trainee, pharmacy technician, intern, or pharmacist, you must now submit a valid Arizona Fingerprint Clearance Card with your application.

If you have a valid Arizona Fingerprint Clearance Card, submit a copy with your application.

If you do not have a valid Arizona Fingerprint Clearance Card, you must obtain one before applying for licensure. To obtain an Arizona Fingerprint Clearance Card, you may apply online at <http://fieldprintarizona.com>. Select the Regular Application – Paid Employee, then select AZ Board of Pharmacy. The statutory reference for the Board is Arizona Revised Statute §32-1904.

For questions, contact the Arizona Department of Public Safety (DPS). You may contact DPS by calling 602/223-2279. DPS office hours are Monday through Friday, 8 AM to 5 PM. Applicants who are not in Arizona must contact DPS for an application packet.

For more information, please review DPS Fingerprint Clearance Card Frequently Asked Questions at www.azdps.gov/services/fingerprint.

Best Practice: Know Who You Are Doing Business With

The Drug Supply Chain Security Act (DSCSA) (Title II of Public Law 113-54) was signed into law on November 27, 2013. The DSCSA outlines critical steps to build an electronic, interoperable system to identify and trace products as they are distributed in the US.

Counterfeit product continues to be a problem and can seriously injure and compromise the health of a patient or consumer. The Board encourages all permit holders to do business **only** with Arizona permit holders. The Board also encourages patients and consumers to purchase **only** from Arizona permit holders. Maintaining permits of the entities you do business with is one way of validating your business partner. This will also assist in closing the loop so that counterfeit product entering the arena is minimized.

Another area of focus is pharmacy to pharmacy and hospital to hospital sharing of inventory. The word “borrow” does not exist. All transactions performed by permit holder to permit holder shall be done via invoice, as stated in R4-23-601(D). This allows for better and accurate record keeping. The Board compliance officers will be looking for this during their inspections.

Mandatory Counseling

Many studies have been published on the importance of patient education/counseling with direct correlation to adherence and patient outcome. Arizona is a **mandatory counseling**

state, as referenced in R4-23-402(B), (C), (D), and (E). There continues to be failure in pharmacists providing this care to the patients they serve. Please let the Board remind you of the Oath of a Pharmacist:

I promise to devote myself to a lifetime of service to others through the profession of pharmacy. In fulfilling this vow:

- ◆ I will consider the welfare of humanity and relief of suffering my primary concerns.
- ◆ I will apply my knowledge, experience, and skills to the best of my ability to assure optimal outcomes for my patients.
- ◆ I will respect and protect all personal and health information entrusted to me.
- ◆ I will accept the lifelong obligation to improve my professional knowledge and competence.
- ◆ I will hold myself and my colleagues to the highest principles of our profession’s moral, ethical and legal conduct.
- ◆ I will embrace and advocate changes that improve patient care.
- ◆ I will utilize my knowledge, skills, experiences, and values to prepare the next generation of pharmacists.

I take these vows voluntarily with the full realization of the responsibility with which I am entrusted by the public.

Disciplinary Actions and Updates – Other Health Boards

Arizona Regulatory Board of Physician Assistants

James G. Morphis, PA #3283 – Interim consent agreement for practice restriction. Respondent is prohibited from engaging in the practice of medicine with physician supervision in the state of Arizona. Respondent shall not return to the practice of medicine under physician supervision until he applies to the Board and demonstrates his ability to safely carry out approved health care tasks and receives the Board’s permission to do so. Effective June 23, 2016.

Arizona Medical Board

Craig W. Tolleson, MD #36928 – Interim consent agreement for practice restriction. Respondent is prohibited from engaging in the practice of medicine in the state of Arizona until he applies to the executive director and receives permission to do so. Respondent may not request release from or modification of this interim consent agreement for practice restriction until he has completed a competency assessment at a Board-approved facility and any recommendations that arise as a result of the assessment. Effective July 15, 2016.