



Arizona State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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Thank You for Your Service, Mr Dennis McAllister!

After 22 years of service to the Board, Dennis McAllister has made the difficult decision to step aside and give someone else an opportunity to serve the great state of Arizona. While on the Board, Dennis represented Arizona as the 2005-2006 president of the National Association of Boards of Pharmacy® and has received many accolades, the most recent being the Bowl of Hygeia Award. Thank you, Dennis, for your service and for guiding the Board in the interest of public safety.



Renewal Time

Since the Board rotates renewals from year to year, please verify your license and/or permit. If your license and/or permit is due to expire by October 31, 2018, then you will need to renew. Please use the Board's online process to renew. If you are an immunizer, please read the "Immunizing FAQs" below.

Immunizing FAQs

Q. How do I get my certificate? Why don't I get a separate certificate for immunizing now? Where is the immunization indicator on my license?

A. The Board no longer issues immunizing certificates separately. If you are an immunizing pharmacist or intern, it will be noted on your license below the license type (ie, pharmacist or intern).



Q. When does the certificate expire?

A. As long as you maintain the required continuing education (CE) and your cardiopulmonary resuscitation (CPR) certificate, the ability to immunize will correspond with your pharmacist license. There is no longer a separate immunizing certificate; therefore, the expiration date is the same as your license expiration date.

Q. How often do I renew my immunizing certificate now?

A. There is no longer a separate immunizing certificate. It will be renewed when your license is due to renew biennially.

Q. What is required to maintain my immunizing certificate? How many CE credits do I need to complete and how often?

A. (1) Current certification in basic CPR; and (2) Completion of a minimum of two contact hours (0.2 CEU) of CE related to immunizations during the two-year renewal period. A pharmacist may use the CE hours required in this subsection as part of the total CE hours required for a pharmacist license renewal.

Q. I went to renew my license and the system asked about my immunizing CE, but I haven't completed it. What do I do?

A. You must complete the minimum of two contact hours (0.2 CEU) of CE related to immunizations prior to renewing.

Q. My current immunizing certificate doesn't expire until 2019, so I haven't completed the CE yet. Is this OK?

A. Unfortunately, you will need to complete the immunization CE prior to renewal. You must complete the minimum of two contact hours (0.2 CEU) of CE related to immunizations prior to renewing.

National Pharmacy Compliance News

October 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.

SAMHSA Publishes Guidance for Treating OUD

To help broaden health care professionals' understanding of medications that can be used to treat Americans with opioid use disorder (OUD), the Substance Abuse and Mental Health Services Administration (SAMHSA) offers guidance on clinical best practices in the February 2018 publication titled *Treatment Improvement Protocol 63, Medications for Opioid Use Disorder*. The publication reviews the use of the three Food and Drug Administration (FDA)-approved medications used to treat OUD – methadone, naltrexone, and buprenorphine – and other strategies and services needed to support recovery for people with OUD.

Additionally, in February 2018, SAMHSA released the publication *Clinical Guidance for Treating Pregnant and Parenting Women with Opioid Use Disorder and Their Infants*, which offers standard approaches for health care professionals. This publication provides evidence-based treatment options, including pharmacotherapy with methadone, buprenorphine, and buprenorphine/naloxone, for pregnant women with OUD. The clinical guidance also helps health care professionals and patients determine the most clinically appropriate action for a particular situation and informs individualized treatment decisions. Both publications can be found in the Publications section of SAMHSA's website at www.samhsa.gov.

FDA Issues Final Guidance Policy on Outsourcing Facilities

In May 2018, FDA issued a new policy designed to address any ambiguity around how to define the physical features and operations of outsourcing facilities. According to FDA Commissioner Scott Gottlieb, MD, the policy in the final guidance, *Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act*, will help to:

- ◆ ensure that compounded drugs are made under appropriate quality standards;
- ◆ provide transparency to patients and health care providers about the standards under which the compounded drugs that they purchase are made; and

- ◆ respond to stakeholder feedback requesting guidance on the meaning of “facility” under section 503B.

In the guidance, FDA explains that a section 503A establishment compounding drugs pursuant to patient-specific prescriptions may be located near or in the same building as the outsourcing facility provided that they are completely separate. As explained in the guidance, the boundaries between the section 503A establishment and outsourcing facility should be clear and may include permanent physical barriers, such as walls or locked doors, and the two operations should not share rooms, equipment, supplies, or pass-through openings (eg, they may not subdivide a room with temporary barriers such as curtains). The guidance further explains that the labeling should clearly identify the compounder who produced the drug. Lastly, the guidance reminds industry and stakeholders that all drug products compounded in an outsourcing facility are regulated under section 503B and are subject to current good manufacturing practice requirements, even if those drug products are compounded pursuant to patient-specific prescriptions. Additional information can be located at www.fda.gov/newsevents/newsroom/fdainbrief/ucm607339.htm.

EU-US Mutual Recognition Agreement Now Operational Between FDA and 12 Member States

In January 2018, FDA confirmed the capability of four more European Union (EU) member states – Czech Republic, Greece, Hungary, and Romania – to carry out good manufacturing practice inspections at a level equivalent to the United States. With the addition of the four EU member states, FDA can now rely on inspection results from 12 EU member states. The mutual recognition agreement between the EU and US to recognize inspections of manufacturing sites for human medicines conducted in their respective territories is progressing as planned, with plans for the agreement to be operational in all EU member states by July 15, 2019, indicates a European Medicines Agency (EMA) press release. In 2017, FDA determined the agency will recognize eight European drug regulatory authorities in Austria, Croatia, France, Italy, Malta, Spain, Sweden, and the United Kingdom as capable of conducting

inspections of manufacturing facilities that meet FDA requirements. The EMA news release, “Four more EU Member States benefit from EU-US mutual recognition agreement for inspections,” can be found in the News and Events section at www.ema.europa.eu.

US Surgeon General Advisory Urges More Individuals to Carry Naloxone

In an April 2018 advisory, US Surgeon General Jerome M. Adams, MD, MPH, emphasizes the importance of more individuals knowing how to use naloxone and keeping it within reach. Surgeon General Adams recommends that family, friends, and those who are personally at risk for an opioid overdose keep the drug on hand. As stated in the advisory, expanding the awareness and availability of naloxone is a key part of the public health response to the opioid epidemic. The Surgeon General advisory on naloxone is part of the Trump Administration’s ongoing effort to respond to the sharp increase among drug overdose deaths, notes a US Department of Health and Human Services (HHS) news release. HHS also has a website, www.hhs.gov/opioids, with resources and information for individuals who want to fight the opioid crisis in their communities or find help for someone in need. The advisory and news release can be found at www.surgeongeneral.gov.

Expanding Pharmacists’ Scope of Practice Linked to Improved Cardiovascular Outcomes

Elevating pharmacy involvement in patient care and using a team-based care model are among the effective strategies for preventing cardiovascular disease that were identified in a new guide developed by the Centers for Disease Control and Prevention’s (CDC’s) Division for Heart Disease and Stroke Prevention (DHDSP). The guide, *Best Practices for Cardiovascular Disease Prevention Programs: A Guide to Effective Health Care System Interventions and Community Programs Linked to Clinical Services*, describes the scientific evidence behind each strategy, including collaborative drug therapy management, enabled by a collaborative practice agreement, and medication therapy management. To be included in the guide, strategies had to be supported by multiple high-quality research studies that demonstrated evidence of effectiveness in controlling blood pressure or cholesterol levels. More details about the best practice strategies along with resources and tools for implementing the strategies identified by CDC’s DHDSP can be found at www.cdc.gov/dhdsp/pubs/guides/best-practices/index.htm.

Pharmacists Are Critical to Drug Supply Chain Integrity, States FIP

Medicines are specialized commodities and, if they are not managed rationally or appropriately, they are equivalent to a dangerous substance, indicates the International Pharmaceutical Federation (FIP). In a May 2018 report, *Pharmacists in the supply chain: The role of the medicines expert in ensuring quality and availability*, FIP provides a global picture of the role of pharmacists in supply chains, the tasks currently undertaken by pharmacists in different countries, and pharmacists’ unique competencies. Based on reviews of literature, survey data, and case studies from nine countries, pharmacists were identified as having expertise that is critical to supply chain integrity. According to FIP, pharmacists and those who are involved in the planning, procurement, manufacture, storage, and distribution of medicines must:

- ◆ consider how to most effectively use the skills of the staff and personnel available;
- ◆ provide and seek training where needed; and
- ◆ keep their systems and role descriptions under review in order to adapt to changing circumstances.

FIP’s report and news release can be located at www.fip.org/news_publications.

Emergency Department Visits for Opioid Overdoses Rose 30%

From July 2016 through September 2017, reports of emergency department (ED) visits for opioid overdoses – including prescription pain medications, heroin, and illicitly manufactured fentanyl – rose 30% in all parts of the US, according to a CDC report. The Midwest saw opioid overdoses increase 70% during this time period. According to the March 9, 2018 *Morbidity and Mortality Weekly Report*, coordinated action between EDs, health departments, mental health and treatment providers, community-based organizations, and law enforcement can prevent opioid overdose and death. People who have had an overdose are more likely to have another; thus, being seen in the ED is an opportunity for action. EDs can provide naloxone, link patients to treatment and referral services, and provide health departments with critical data on overdoses. The CDC report, “Vital Signs: Trends in Emergency Department Visits for Suspected Opioid Overdoses — United States, July 2016–September 2017,” can be accessed at <http://dx.doi.org/10.15585/mmwr.mm6709e1>.

Disciplinary Actions and Updates

Pharmacists

Linda Trinh (S020176) – Consent agreement and order for probation and civil penalties. Consent agreement to include six months stayed suspension, five years of probation, and a \$9,000 civil penalty.

Kevin T. Tran (S011475) – Consent agreement for civil penalty and CE. Consent agreement to include a \$1,000 civil penalty and six hours of CE in patient safety and immunization.

Jiten Sidhu (S020833) – Consent agreement and order for probation and civil penalties. Consent agreement to include six months stayed suspension, five years of probation, and a \$9,000 civil penalty.

Chris Alan Cavalcant (S016227) – Consent agreement and order for probation. Consent agreement to include a Professionals Assisting Professionals of Arizona contract and five years of probation.

Lucas Kimang'a Nyabero (S016395) – Consent agreement for civil penalty, administrative fees, and order for probation. Consent agreement includes a \$25,000 civil penalty and \$6,300 in administrative fees. Respondent's NewSpring Pharmacy permit placed on probation.

Mohamed S. Hassanein-Elembabi (S016520) – Consent agreement and order of suspension followed by probation. License suspended for 18 months followed by probation for a minimum of four years. The consent agreement also includes \$22,000 in administrative fees and a total of \$100,000 in civil penalties.

Mohamed Eslam Elmissirey (S015982) – Consent agreement and order of suspension followed by probation. License retroactively suspended for six months then placed on probation for a minimum of five years. The consent agreement also includes an \$18,000 civil penalty and \$2,900 in administrative fees.

Michael Abraham (S012799) – Interim consent agreement for voluntary suspension of license and evaluation for substance use disorder. License suspended.

Kevin Francis (S014977) – Consent agreement for civil penalty and disciplinary CE. Consent agreement to include a civil penalty of \$500 and three hours of CE in patient counseling/patient safety.

Harold G. Shapiro (S010298) – Consent agreement for CE and civil penalty. Consent agreement to include a civil penalty of \$1,000 and six hours of CE in patient safety/medication errors and anticoagulants.

Damian Hohensee (S013084) – Interim findings of fact, conclusions of law, and order for summary suspension of license. License summarily suspended.

Ashwin Waghray (S015225) – Consent agreement for civil penalty and CE. Consent agreement includes a civil penalty for \$2,000 and 15 hours of CE in wet lab and record keeping.

Monte Weston Lewis (S019926) – Interim consent agreement and order for voluntary suspension of license. License suspended.

Pharmacy Technicians

Berlin Bellows (T034979) – Consent agreement and order for surrender. License surrendered.

Vickie Charlene Hilton (T060694) – Consent agreement for civil penalty. Pharmacy technician license issued after applicant

entered into a consent agreement. Required to pay \$500 civil penalty.

Jennifer Diosdado (T060693) – Consent agreement for civil penalty. Pharmacy technician license issued after applicant entered into a consent agreement. Required to pay \$500 civil penalty.

Roxanne Marie Curley (T057091) – Consent agreement for civil penalty. Pharmacy technician trainee license issued after applicant entered into a consent agreement for civil penalty. Required to pay \$250 civil penalty.

Kasie Dawn Hofhines (T060802) – Consent agreement for civil penalty. Pharmacy technician trainee license issued after applicant entered into a consent agreement for civil penalty. Required to pay \$250 civil penalty.

Aaron Joseph Meyer (T055914) – Consent agreement and order for voluntary surrender. License surrendered.

Diana L. Anders (T055284) – Consent agreement and order for voluntary surrender. License surrendered.

Benjamin Neil Valentine (T045671) – Denial of application for licensure as a pharmacy technician.

Mauricio Paras Abao (T016221) – Decision and order. License revoked.

Dominik Elijah Torres (T056097) – Consent agreement and order for voluntary surrender. License surrendered.

Keaton Benton Brown (T061845) – Consent agreement for civil penalty. Pharmacy technician license issued after applicant entered into a consent agreement for civil penalty. Required to pay \$250 civil penalty.

Juan Jose Cantu (T061924) – Consent agreement for civil penalty. Consent agreement includes a civil penalty for \$250.

Aaron Kiel (T062007) – Consent agreement for civil penalty. Pharmacy technician trainee license issued after applicant entered into a consent agreement for civil penalty. Required to pay \$250 civil penalty.

Alana Maria Flowers (T062019) – Consent agreement for civil penalty. Pharmacy technician license issued after applicant entered into a consent agreement for civil penalty. Required to pay \$250 civil penalty.

Intern

Brian Witmer (I011630) – Decision and order. License revoked.

Permits

Diabetic Apothecary, LLC (Y006969) – Consent agreement for civil penalty. Consent agreement includes a civil penalty for \$2,000.

Walgreens Drug #06666 (Y003513) – Consent agreement for civil penalty. Consent agreement includes a civil penalty for \$3,000.

Sun City Pharmacy (Y005538) – Consent agreement and order for surrender. Permit surrendered.

Grand Pharmacy (Y006618) – Consent agreement and order for surrender. Permit surrendered.

St. Joseph Pharmacy (Y006673) – Consent agreement and order for surrender. Permit surrendered.

NewSpring Pharmacy LLC (Y005594) – Consent agreement for civil penalty, administrative fees, and order for probation. Permit placed on probation for a minimum of two years. Permit

Continued from page 4

holder must pay a \$25,000 civil penalty and \$6,300 in administrative fees.

Walmart Pharmacy #10-1370 (Y003196) – Consent agreement for civil penalty. The consent agreement includes a civil penalty of \$500.

Application Status Updates

James Troy Bayne – Denial of application for licensure as a pharmacy technician trainee.

Evelynn Ann Bitsinni – Denial of application for licensure as a pharmacy technician trainee.

Justin Caligari – Denial of application for licensure as a pharmacy technician trainee.

Devin Alexander Noriega – Denial of application for licensure as a pharmacy technician trainee.

Tiana Nicole Johnson – Denial of application for licensure as a pharmacy technician trainee.

Katherine Marie Kerce – Denial of application for licensure as a pharmacy technician trainee.

Saul Benjamin Moran Vega – Denial of application for licensure as a pharmacy technician trainee.

Victoria Crystal Alegria – Denial of application for licensure as a pharmacy technician trainee.

Brianna McFarland – Decision and order. Denial of application for licensure as a pharmacy technician.

Disciplinary Actions and Updates – Other Health Boards

Arizona Medical Board

Jujhar S. Bains, MD #54547 – Interim practice limitation (non-disciplinary). Physician 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 Board and receives its affirmative permission to do so.

Karen B. Barcklay-Dodson, MD #29446 – 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.

John L. Kallmeyer, MD #8383 – Practice limitation (non-disciplinary). Physician is prohibited from engaging in the practice of medicine until he applies to the Board and receives its affirmative permission to do so.

Susan M. Kunkel, MD #52089 – Interim 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 she applies to the Board and receives its affirmative permission to do so.

John P. Moran, MD #36042 – 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.

Darrell Kent Reed, MD #45378 – Interim 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.

Glenn G. Robertson, MD #33045 – Effective June 25, 2018, respondent's license to practice allopathic medicine in Arizona is summarily suspended in that 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.

Subodh Sumanlal Shroff, MD #37588 – Effective August 23, 2018, respondent's license to practice allopathic medicine in Arizona is summarily suspended in that 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.

Herman Bradley Smith, MD #21590 – Interim 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.

Arizona Regulatory Board of Physician Assistants

Michael M. Abraham, PA #5934 – Interim practice restriction. Respondent is prohibited from engaging in health care tasks with physician supervision in the state of Arizona as set forth in A.R.S. §32-2501 (13) until he applies to the executive director and receives permission to do so.

Kerry Darwin Malin, PA #5167 – Interim practice restriction. Respondent is prohibited from prescribing controlled substances (CS) in the state of Arizona pending the outcome of a formal interview or formal hearing in this matter.

Nathaniel Alan Welly, PA #3406 – Interim practice restriction. Respondent is prohibited from prescribing CS in the state of Arizona until he receives permission to do so. Respondent may not request release from, or modification of, this interim consent agreement until he has completed a Board staff-approved intensive, in-person, continuing medical education course in CS prescribing.

Naturopathic Physicians Medical Board

Marie Niechwiadowicz, NMD #08-1055 – Interim practice restriction. Respondent's license is immediately suspended, and respondent shall not practice as a naturopathic physician until the Board renders a final decision in the case.

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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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