



Arizona State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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Law Change: E-Prescribing CS and Physician Assistant Prescriptive Authority

The Board is pleased to report that Governor Doug Ducey signed House Bill (HB) 2075 into law, which covers e-prescribing, exceptions, and deadlines. It is an emergency measure made retroactive to December 31, 2018. HB 2075 delays e-prescribing requirements for all counties until January 1, 2020. Additionally, the bill reinstates a Board-certified physician assistant’s ability to issue a 30-day prescription for Schedule II, III, IV, and V controlled substances (CS) that are opioids and benzodiazepines.

HB 2075 contains major provisions that:

- ◆ move the 2019 implementation dates to January 1, 2020, for all counties;
- ◆ allow for written prescriptions if the e-prescribing system is not operational or available in a timely manner, in which case the medical practitioner shall indicate on the written prescription order that the electronic prescribing system or pharmacy management system is not operational or available (occurrence must be noted in records maintained by the medical practitioner and pharmacy for a period of time set by the respective board);
- ◆ exempt requirements for Indian Health Service and federal facilities;
- ◆ eliminate the waiver process through the Board but provide rulemaking authority in consultation with a task force to add additional exceptions;

- ◆ delay e-prescribing requirements for veterinarians until e-prescribing software is widely available;
- ◆ allow for prescriptions to be faxed if the prescription is compounded for direct administration to a patient, residents of a long-term care facility, or hospice patients;
- ◆ resolve a statutory conflict that inadvertently imposed a prohibition on physician assistants prescribing more than a 72-hour dosage of opioids or benzodiazepines; and
- ◆ contain a retroactive clause to December 31, 2018, so the legislation takes effect immediately once it becomes law.

Pharmacy Technician Trainee Licenses: How to Reapply for an Extension

Pharmacy technician trainees with licenses that have expiration dates on or before July 31, 2019, are eligible to reapply for a two-year extension of their licenses, up to 60 days before their licenses expire.

Note: No applications that reapply for extensions will be accepted after July 31, 2019. Pharmacy technician trainees with licenses expiring after July 31, 2019, are not eligible to reapply for extensions.

Reapplying for an extension is not available for a technician trainee whose license has already expired or has already been extended. An extension is only allowed one time.

Technician trainees who are granted reapply extensions will receive a one-time, two-year extension of their licenses. The two-year reapply license fee is \$36, and it can be paid using a check or money order made payable to Arizona State Board of Pharmacy. **Neither an online application nor credit/debit payments are available.** Reapply applications may be mailed or dropped off at the Board office, Monday through Friday, 8 AM to 5 PM, except state holidays. Payments are not accepted after 4 PM. Processing may take three to four weeks. If the technician trainee license expires, the technician trainee may not work until he or she receives a technician license. **Note: A reapply application is not the same as a renewal.**

Trainee License Holders Not Eligible for Reapply Application

Currently licensed pharmacy technician trainees whose licenses expire after July 31, 2019, are required to take and pass the Pharmacy Technician Certification Board (PTCB) exam or the Exam for the Certification of Pharmacy Technicians (ExCPT). Once they have passed the exam, they must [apply for a pharmacy technician license](#).

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National Pharmacy Compliance News

April 2019



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 Launches Pilot Program to Improve Security of Drug Supply Chain With an Innovative Approach

Food and Drug Administration (FDA) has launched a pilot program allowing participants representing the various parts of the drug supply chain to pilot innovative and emerging approaches for enhanced tracing and verification of prescription drugs in the United States' supply chain. The program is in line with FDA's ongoing efforts to prevent suspect and illegitimate products from entering the supply chain, according to an [FDA press release](#). Eligible manufacturers, repackagers, and other stakeholders can apply to participate in the program, which will inform the development of the enhanced electronic, interoperable track-and-trace system for industry set to go into effect in 2023 in accordance with the Drug Supply Chain Security Act (DSCSA), enacted by Congress on November 27, 2013.

The pilot technologies of this program may become part of FDA's enhanced expectations for reliable track-and-trace systems, which will be designed to reduce diversion of drugs distributed domestically and to keep counterfeit drugs from entering the supply chain. The DSCSA pilot project program is intended to help identify and evaluate the most efficient processes to comply with and apply drug supply chain security requirements and will aid in identifying attributes the system will need for enhanced product tracing and verification, as well as electronic means to share the information. FDA recently issued draft guidance on the use of product identifiers with a unique serial number to improve verification down to the package level. FDA has also provided draft guidance for verification systems to quarantine and investigate suspect and illegitimate drugs.

Additional information on the FDA pilot program is available in a February 8, 2019 announcement in the [Federal Register](#).

FDA Announces New Efforts to Increase Oversight and Strengthen Regulation of Dietary Supplements

Noting that three in four Americans now take at least one dietary supplement on a regular basis, and that the dietary supplement industry has expanded to include as many as 80,000 different products for consumers, FDA Commissioner Scott Gottlieb, MD, has announced new plans to increase the agency's oversight of dietary supplements.

These initiatives include communicating to the public as soon as possible when there is a concern about a dietary supplement on the market, ensuring that the regulatory framework is flexible enough to adequately evaluate product safety, and continuing to work closely with industry partners. FDA is also developing new enforcement strategies to respond to entities that violate standards established under the Dietary Supplement Health and Education Act of 1994.

On February 11, 2019, FDA sent 12 warning letters and five online advisory letters to foreign and domestic companies that are illegally selling more than 58 products. The products are illegally marketed as unapproved new drugs that make unproven claims about preventing, treating, or curing Alzheimer's disease, as well as a number of other serious diseases and health conditions, such as diabetes and cancer. In his statement, Gottlieb noted that most stakeholders in the industry act responsibly, but he expressed concern over the ability of bad actors to exploit the system by providing potentially dangerous products and making unproven or misleading claims about the health benefits supplements may offer.

FDA is planning a public meeting on this topic during the second quarter of 2019. For more information, view the FDA statement at <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm631065.htm>.

Trump Administration Releases National Drug Control Strategy to Reduce Drug Trafficking and Abuse

As the opioid crisis continues to claim the lives of tens of thousands of Americans each year, the Office of National Drug Control Policy has released its *National Drug Control Strategy*. The *Strategy* breaks down the administration's priorities in addressing the crisis, with an emphasis on three areas: prevention, treatment and recovery, and reducing availability.

- ◆ **Prevention** efforts are focused on educating both consumers and caregivers about the dangers of opioid misuse and include a new national media campaign, continued efforts to expand prescription monitoring programs (PMPs), and improving the ability of state, local, and tribal communities to identify and prevent substance abuse.
- ◆ **Treatment and recovery recommendations** in the *Strategy* include improving access to naloxone, improving evidence-based addiction treatment, and eliminating barriers for accessing treatment.

- ◆ **Reducing availability** strategies are focused on disrupting illegal supply chains, defeating drug traffickers, increased cooperation with international partners, and combating illegal internet drug sales.

The document notes that the “most important criterion of success” is saving lives and calls for the federal government to work closely with state and local governments, as well as other stakeholders. Additional information, including the full strategy document, is available on the White House website at <https://www.whitehouse.gov/opioids>.

National Association of Boards of Pharmacy® (NABP®) and its member boards of pharmacy remain committed to advancing best practices for PMPs in the interest of public health. NABP’s PMP data sharing system, NABP PMP InterConnect®, facilitates the secure transfer of PMP data across state lines and provides an effective means of combating drug diversion and drug abuse nationwide. In addition, NABP and its member boards continue efforts to educate consumers about prescription drug safety. The NABP AWARD[®] Prescription Drug Safety Program’s Drug Disposal Locator Tool has more than 6,000 disposal locations and continues to add new locations to provide consumers with a safe way to dispose of medication and help prevent misuse and abuse of prescription medications. For more information about PMP InterConnect and the AWARD program, visit the Initiatives section of the NABP website at www.nabp.pharmacy.

New Study Predicts Opioid Epidemic Will Worsen Over the Next Decade

More than 700,000 people will die from opioid overdoses between 2016 and 2025, and annual overdose deaths will reach nearly 82,000 by 2025, estimates a new study published to *JAMA Network Open*. The estimate is based on an analysis of data from the National Survey on Drug Use and Health and the Centers for Disease Control and Prevention from 2002 to 2015.

Researchers also projected that intervention efforts focused on lowering the incidence of prescription opioid misuse would help to reduce the number of deaths 3.8% to 5.3%, a figure the researchers described as “modest,” due to the changing nature of the opioid crisis. The study notes that more people are directly initiating opioid use with illicit opioids rather than prescription drugs, and illicit opioids have become more lethal with the availability of illegally manufactured fentanyl.

The researchers encourage policymakers to take “a stronger and multipronged approach” to reduce the impact of the ongoing opioid overdose epidemic. The full article is available at <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2723405>.

FDA Warns of Potential Blood Pressure Medication Shortages Due to Recalls

FDA is warning health care providers and consumers of a shortage of angiotensin II receptor blockers, commonly used to treat high blood pressure. A growing list of medications containing valsartan, losartan, and irbesartan have been recalled from the market for containing an impurity that may present a cancer risk to patients. The issue was first detected in the summer of 2018, according to a statement posted to the FDA website. Since then, FDA has placed a Chinese manufacturer of the active ingredient on import alert to stop their imports, and FDA is working with other manufacturers to recall affected medications.

In the statement, FDA notes that the risk to individual patients remains very small, but that there is still reason to be concerned about the potential health risks. Medications with these impurities are believed to have been in the market for about four years.

“Now that these risks are identified, we’re applying what we’ve learned to the evaluation of similar manufacturing processes where we now know these risks could arise,” the statement notes. The FDA press release is available at <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm629796.htm>.

FDA Releases Two Draft Guidances Related to REMS Programs

FDA has released two new draft guidances to ensure risk mitigation programs put in place for certain drugs and biologics, as required for approval, are working. The agency’s primary risk management tool is FDA-approved product labeling. However, in limited cases, FDA may require a Risk Evaluation and Mitigation Strategy (REMS) to help ensure a drug’s benefits outweigh its risks.

The following guidances relate to the assessment of REMS programs:

- ◆ **REMS Assessment: Planning and Reporting Guidance for Industry** describes how to develop a REMS Assessment Plan.
- ◆ **Survey Methodologies to Assess REMS Goals That Relate to Knowledge Guidance for Industry** provides recommendations on conducting REMS assessment surveys to evaluate patient or health care provider knowledge of REMS-related information.

FDA states that the goal in providing this guidance for REMS is to ensure constant improvement of their safety programs and establish the most efficient and effective programs moving forward, to optimize patient care and keep consumers safe and healthy. More information on REMS is available on the FDA website at <https://www.fda.gov/drugs/drugsafety/remis>.

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A PTCB or ExCPT certification alone does not qualify technicians to work in an Arizona pharmacy; a technician must have a license from the Board. If an individual's trainee license expires, he or she may not work as a trainee or a pharmacy technician until he or she receives a pharmacy technician license.

Contact PTCB or ExCPT for information on exam dates, times, and locations. Tests are not given by the Board.

- ◆ **PTCB:** 1-800/363-8012
- ◆ **ExCPT:** 1-800/449-9092

Allow six to eight weeks for an online application to process. A hard copy application may take 10 to 12 weeks. If an application is not complete, it may take longer to process.

Read the [Pharmacy Technician License Application Requirements document](#) for more information.

Should trainees find themselves between licenses, review the Board's list of [clerk duties](#) they may perform without a license.

Pharmacy Reporting Requirements

The following is an excerpt from Arizona Administrative Code that outlines when administrators and pharmacists must make a report to the Arizona Department of Health Services.

R9-6-205. Reporting Requirements for a Pharmacist or an Administrator of a Pharmacy

- A. A pharmacist who fills an individual's initial prescription for two or more of the drugs listed in subsection (B) or an administrator of a pharmacy in which an individual's initial prescription for two or more of the drugs listed in subsection (B) is filled shall, either personally or through a representative, submit a report, in a Department-provided format, that complies with subsection (C) to the Department within five working days after the prescription is filled.
- B. Any combination of two or more of the following drugs when initially prescribed for an individual, triggers the reporting requirement of subsection (A):
 1. Isoniazid,
 2. Streptomycin,
 3. Any rifamycin,
 4. Pyrazinamide, or
 5. Ethambutol.
- C. A pharmacist or an administrator of a pharmacy shall submit a report required under subsection (A) that includes:
 1. The following information about the individual for whom the drugs are prescribed:
 - a. Name,
 - b. Address,
 - c. Telephone number, and
 - d. Date of birth; and
 2. The following information about the prescription:
 - a. The name of the drugs prescribed,
 - b. The date of prescription, and
 - c. The name and telephone number of the prescribing health care provider.

Immunization CE Requirements – Update

The continuing education (CE) requirement for immunizing pharmacists has changed from five CE hours in five years to two

CE hours every two years. The Board has also updated the CE requirement language and implemented the immunizing designation on pharmacist licenses. A separate immunizing certificate is no longer needed. If you are a new immunizer, you will still need to submit an application for certification to perform immunizations by visiting https://pharmacy.az.gov/sites/default/files/editors_choice_attachments/application%20%28immunization%29.pdf.

The aligning of the immunization certificate and CE requirement to the pharmacist license will alleviate the stress of tracking one more thing and further streamlines the process. The implementation of this new procedure and requirement is now in effect. If you are an immunizing pharmacist, you will need to complete your CE prior to renewing your license this year and prior to every renewal cycle going forward.

Disciplinary Actions and Updates Pharmacists

Brian J. Wambold (S013902) – Interim consent agreement and order for voluntary suspension of license and substance use/abuse evaluation.

Eric Curtis Boel (S018886) – Consent agreement for civil penalty. The consent agreement includes a \$500 civil penalty.

Peter Jin Chang (S017715) – Consent agreement for voluntary surrender. License voluntarily surrendered.

Ashley A. Mohn (S020430) – Consent agreement and order for civil penalty and CE. The consent agreement includes a \$250 civil penalty.

Stan Nikitin (S018830) – Consent agreement for civil penalty. The consent agreement includes a \$250 civil penalty.

Technicians

Rachael Diane Randolph (T047324) – Consent agreement and order for surrender. License surrendered.

Paul Romeo Tamou (T027377) – Consent agreement for civil penalty. The consent agreement includes a \$500 civil penalty.

Guy Owens (T063462) – Consent agreement for civil penalty. License issued upon entry into consent agreement and payment of a \$250 civil penalty.

Ingni Sabrina Osorno (T059963) – Consent agreement for civil penalty. The consent agreement includes a \$250 civil penalty.

Crystal DeAnn Richards (T055399) – Consent agreement for civil penalty. The consent agreement includes a \$250 civil penalty.

Kandance J. Saucedo (T059202) – Consent agreement for civil penalty. The consent agreement includes a \$250 civil penalty.

Samantha Jean Walker (T063642) – Consent agreement for civil penalty. License issued upon entry into consent agreement and payment of a \$250 civil penalty.

Geneva Bighumb (T063669) – Consent agreement for civil penalty. License issued upon entry into consent agreement and payment of a \$250 civil penalty.

John David Fugate (T043391) – Consent agreement for probation. License placed on probation for five years.

Kyle Whitfield (T063668) – Consent agreement for civil penalty. License issued upon entry into consent agreement and payment of a \$250 civil penalty.

Tonia Rae Attakai (T007280) – Findings of fact, conclusions of law, and Board order. License revoked.

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Diana L. Donnersbach (T033271) – Findings of fact, conclusions of law, and Board order. License revoked.

Priscilla Torres (T003079) – Interim consent agreement for voluntary suspension of license.

Dustin Richard Bellah (T010829) – Consent agreement and order for surrender. License voluntarily surrendered.

Cheryl L. Tso (T055972) – Consent agreement for civil penalty. The consent agreement includes a \$250 civil penalty.

Antonio A. Rodriguez (T056387) – Consent agreement for civil penalty. The consent agreement includes a \$250 civil penalty.

Katia Erin Begay (T036774) – Consent agreement for civil penalty. The consent agreement includes a \$250 civil penalty.

Permits

Banner Compounding Pharmacy (Y005621 & M000626) – Interim consent agreement and order for an inspection by the National Association of Boards of Pharmacy's® Verified Pharmacy Program® and state inspections.

Walgreens #10111 (Y004843) – Consent agreement and order for civil penalty. The consent agreement includes a \$6,000 civil penalty.

AZ Price Line Inc, dba Skyline Distributors (W002624) – Consent agreement and order for civil penalty. The consent agreement includes a \$1,000 civil penalty.

Application Status Updates

James Isaac De Anda – Denial of application for licensure as a pharmacy technician trainee.

Kristen Homeyer – Denial of application for licensure as a pharmacy technician trainee.

Disciplinary Actions and Updates – Other Health Boards

Arizona Medical Board

Terrence J. Adam, MD #33382 – 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.

Sharron Jones-Daggett, MD #47737 – 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.

Karnail S. Dhillon, MD #27921 – Respondent is restricted in that he is prohibited from prescribing CS until he has completed the required continuing medical education, enters into an agreement with a Board-approved monitor to conduct chart reviews, and provides satisfactory proof of compliance with these requirements. Effective February 5, 2019.

Rogelio D. Naranja, MD #13156 – Surrender of license effective December 5, 2018.

David E. Nielsen, MD #54814 – 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.

Richard M. Roberts, MD #54596 – 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 Board's executive director and receives permission to do so.

Ava Rose, MD #50321 – Interim practice restriction. Respondent is prohibited from prescribing CS in the state of Arizona until she requests release or modification from this order.

Marvin C. Schneider, MD #4036 – Surrender of license effective January 11, 2019.

Subodh S. Shroff, MD #37588 – Surrender of license effective February 5, 2019.

Lisa A. Sparks, MD #13545 – Interim practice restriction. Respondent is prohibited from prescribing CS in the state of Arizona until she requests release or modification from this order.

Craig W. Tolleson, MD #36928 – Revocation of license effective February 15, 2019.

Jill R. Utley, MD #42779 – 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.

Kirk G. Williams, MD #13691 – 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 Naturopathic Physicians Medical Board

Michael Miller, ND #12-1313 – Surrender of license effective November 6, 2018.

Arizona Regulatory Board of Physician Assistants

Brian Arno Cody, PA #2142 – Interim practice limitation (non-disciplinary). Respondent is prohibited from engaging in the practice of medicine in the state of Arizona as set forth in A.R.S. §32-2501 (13) until he applies to the Board's executive director and receives affirmative permission to do so. Respondent may not apply for relief from this practice limitation until he has completed any current treatment program, has been found safe to perform health care tasks, and the Board is in receipt of any discharge report and recommendations for aftercare. This order supersedes a previous interim practice limitation.

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