



Arizona State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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Welcome and Congratulations to New Board Members

Lorri Walmsley, RPh, has been employed as a pharmacist for Walgreens in Arizona in a variety of positions since she graduated from The Ohio State University in 2000. In her current role as senior manager of pharmacy affairs, Lorri works as the liaison to boards of pharmacy in the western half of the United States and is responsible for providing feedback on proposed rules and boards' activities. Lorri is a past president of the Arizona Pharmacy Association (AzPA) and has been involved with a number of other state and national pharmacy organizations. She is very passionate about pharmacy policy advocacy that expands access for patients to high-quality pharmacy services.



Theodore G. Tong, PharmD, RPh, is the R. Ken Coit Endowed Chair professor at the University of Arizona College of Pharmacy. Over the course of his professional pharmacy career in Arizona, which began in 1982, he served as director of the Arizona Poison and Drug Information Center from 1982 to 2005, and associate dean of student affairs at the University of Arizona from 1987 to 2018. He received his doctor of pharmacy degree from the University of California San Francisco School of Pharmacy in 1969 and is a



licentiate in pharmacy in California and Arizona. Theodore is a fellow of the American Pharmacists Association and the American Academy of Clinical Toxicology. He served as a member of the US Food and Drug Administration Advisory Committee on Nonprescription Drugs from 1992 to 1997; the US Pharmacopeial (USP) Convention Committee on Clinical Toxicology and Drug Abuse from 1990 to 1995; and the USP Nomenclature, Labeling, and Safety Committee from 2010 to 2015. As a member of AzPA, he was recognized with the Arizona Pharmacist of the Year Award in 1999, the Bowl of Hygeia Community Service Award in 2006, was inducted into the AzPA Hall of Fame in 2014, and was an Eli Schlossberg Award honoree in 2018. Theodore resides in Tucson, AZ.

Thank You for Your Service

The Board would like to thank **Tom Van Hassel, RPh**, for 15 years of service. Tom has played a key role in shaping pharmacy in Arizona today during his time with the Board. Throughout his career, he has mentored and will continue to mentor his fellow pharmacists. Though Tom will no longer be on the Board, he will continue to shape the future of pharmacy. Good luck, Tom, and thank you for your service.



Opioid Dispensers' Required Continuing Education

All pharmacists renewing licenses in 2019 and going forward must comply with the following statute.

Section 32-3248.02. Health professionals; substance use or addiction continuing medical education

A health professional who is authorized under this title to prescribe schedule II controlled substances and who has a valid United States drug enforcement administration registration number or who is authorized under chapter 18 of this title to dispense controlled substances shall complete a minimum of three hours of opioid-related, substance use disorder-related or addiction-related continuing medical education each license renewal cycle . . . as part of any continuing education requirements for that health professional.

Proposed Rules Packet – Public Comment

Public comments will be open for two rules packets on February 6, 2019, and February 7, 2019. The rules packets will be posted

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National Pharmacy Compliance News

January 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.

Final Guidance Documents Address FDA Policies Related to DSCSA

To help ensure that prescription drug products are identified and traced properly as they move through the supply chain in compliance with federal law, Food and Drug Administration (FDA) issued two final guidance documents related to the Drug Supply Chain Security Act (DSCSA). Released on September 19, 2018, the following final guidance documents will help ensure there are no disruptions in the supply chain as manufacturers and repackagers include a product identifier on the package or case.

- ◆ *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy* addresses industry-wide readiness for implementation of the new requirements aimed at enhancing the security of the drug supply chain. As the agency continues to work with stakeholders to ensure proper implementation of the law, this guidance document specifies FDA's one-year delay in enforcing the manufacturers' requirement to include a product identifier on the package or case of products to November 27, 2018.
- ◆ *Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier* outlines the circumstances in which packages and cases of product that were in the supply chain before the November 2018 product identifier requirement are considered grandfathered. The grandfathering policy describes the circumstances under which products already in the supply chain can remain in distribution without being relabeled with a product identifier.

The final guidance documents can be found at www.fda.gov/newsevents/newsroom/fdainbrief/ucm621095.htm.

First FDA-Approved Drug Containing Extract From Cannabis Plant to Be Placed in Schedule V

On September 27, 2018, the United States Department of Justice and Drug Enforcement Administration (DEA) announced that Epidiolex® – which contains cannabidiol, a chemical constituent of the cannabis plant, and is the first FDA-approved drug to contain a purified extract from the plant – is being placed in Schedule V of the Con-

trolled Substances Act. FDA approved Epidiolex for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older on June 25, 2018. Additional information is available in the announcement at www.dea.gov/press-releases/2018/09/27/fda-approved-drug-epidiolex-placed-schedule-v-controlled-substance-act.

ASHP Guidelines Provide Recommendations for Preventing Patient Harm From Medication Errors

New guidelines from the American Society of Health-System Pharmacists (ASHP) describe opportunities for pharmacists on interprofessional teams to prevent errors across the continuum of care in hospitals and health systems. The “ASHP Guidelines on Preventing Medication Errors in Hospitals” are intended to apply to the acute care setting because of the special collaborative processes established in this setting. However, these guidelines may be applicable to practice settings outside of the acute care setting, especially in health systems.

Further, the ASHP press release notes that the guidelines address numerous areas in the medication-use process where errors may occur, including: patient admission; selection and procurement; storage; ordering, transcribing, and reviewing; preparation; dispensing; administration; monitoring; evaluation; and patient discharge. Published in the October 1, 2018 issue of the *American Journal of Health-System Pharmacy*, the guidelines are available at www.ajhp.org/content/75/19/1493. ASHP's October 2, 2018 press release can be found in the News section at www.ashp.org.

FDA's Final Guidance Documents Address Compounding and Repackaging of Radiopharmaceuticals

On September 26, 2018, FDA published the final guidance titled *Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities*. In this final guidance for industry, FDA sets forth its policy regarding compounding and repackaging of radiopharmaceuticals for human use by entities that are registered with FDA as outsourcing facilities. This guidance describes how FDA generally intends to apply section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to radiopharmaceuticals compounded by outsourcing facilities.

In addition, this guidance describes the conditions under which FDA generally does not intend to take action for violations of certain provisions of the FD&C Act when an outsourcing facility repackages radiopharmaceuticals, according to the *Federal Register* notice at www.gpo.gov/fdsys/pkg/FR-2018-09-26/pdf/2018-20901.pdf.

At the same time, FDA published the final guidance titled *Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities*. This guidance sets forth FDA's policy regarding compounding and repackaging of radiopharmaceuticals for human use by state-licensed nuclear pharmacies, federal facilities, and other entities that hold a radioactive materials license for medical use issued by the Nuclear Regulatory Commission or by an Agreement State. Because such radiopharmaceuticals are not eligible for exemptions from provisions of the FD&C Act related to the production of drugs, FDA is issuing this guidance to describe the conditions under which it generally does not intend to take action for violations of certain provisions of the FD&C Act when these entities compound or repackage radiopharmaceuticals. More details are available in the *Federal Register* notice at www.gpo.gov/fdsys/pkg/FR-2018-09-26/pdf/2018-20902.pdf.

Pharmacy Toolkit Encourages Conversations With Patients About Prescription Opioids

In collaboration with its pharmacy partners and several state pharmacy associations, Allied Against Opioid Abuse (AAOA) developed a Pharmacy Toolkit to help pharmacists engage and educate patients about the safe use, storage, and disposal of pain medicines. The AAOA Pharmacy Toolkit includes resources to help pharmacists raise awareness among patients about their rights, risks, and responsibilities associated with prescription opioids. These resources include: a pharmacy display, patient handout, patient engagement guide, tips for talking with patients and caregivers, prescriber engagement guide, safe storage and disposal training, and social graphics. To learn more about the Pharmacy Toolkit and to obtain these resources, visit AAOA's website at <https://againstopioidabuse.org>.

Biosimilars Added to FIP's Policy on Pharmacists' Right to Substitute a Medication

To account for the emergence of biological medicines and their biosimilars onto the medical landscape, the International Pharmaceutical Federation (FIP) has added

biosimilars to its policy on pharmacists' right to substitute one medicine for another. The revised Statement of Policy titled "Pharmacist's authority in pharmaceutical product selection: therapeutic interchange and substitution" includes the core principles of the original statement and the following:

- ◆ generic substitution is recommended as part of the pharmacist's dispensing role;
- ◆ pharmacists should be provided with bioavailability data by regulatory authorities and manufacturers; and
- ◆ a medicine should only be substituted with a product containing a different active ingredient in agreement with the prescriber.

According to FIP's October 2, 2018 press release, the use of generic names is still encouraged, but the revised statement gives focus to the use of international nonproprietary names. The full Statement of Policy and press release are available at www.fip.org in their respective sections.

FDA Offers CE Course on Reducing Hypoglycemic Events in Patients With Type 2 Diabetes

FDA is offering a free, one-hour continuing education (CE) course for health care providers (physicians, pharmacists, nurses, and others) about the reduction of hypoglycemic events in patients with Type 2 diabetes. The course, *Leveraging Health Literacy and Patient Preferences to Reduce Hypoglycemic Events in Patients with Type 2 Diabetes*, will describe the prevalence of hypoglycemic events and identify risk factors leading to an event. Available for credit through October 31, 2020, this course will introduce methods of assessing health literacy and numeracy of patients and caregivers; review effective ways to incorporate patient preferences into care plans; and list action steps to reduce the likelihood of a hypoglycemic event for high-risk patients. To participate in this CE course, visit <http://fdapasediabetes.e-paga.com>.

The FDA Center for Drug Evaluation and Research (CDER) is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education (CPE). This program meets the criteria for one contact hour (0.1 CEU) of CPE credit. The ACPE Universal Activity Number for this knowledge-based activity is 0453-9999-17-449-H01-P. Further, FDA's CDERLearn in the CDER offers a variety of learning opportunities, which can be found at www.fda.gov/Training/ForHealthProfessionals/ucm545645.htm.

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on the Board website prior to the public comment dates for your review.

Notifying the Board

Recently, the Board identified that many licensed pharmacists, interns, technicians, and technician trainees have not been reporting criminal charges. Below you will find the language requiring you to notify the Board within 10 days of charges.

Section 32-3208. Criminal charges; mandatory reporting requirements; civil penalty

- A. A health professional who has been charged with a misdemeanor involving conduct that may affect patient safety or a felony after receiving or renewing a license or certificate must notify the health professional's regulatory board in writing within ten working days after the charge is filed.
- B. An applicant for licensure or certification as a health professional who has been charged with a misdemeanor or involving conduct that may affect patient safety or a felony after submitting the application must notify the regulatory board in writing within ten working days after the charge is filed.
- C. On receipt of this information the regulatory board may conduct an investigation.
- D. A health professional who does not comply with the notification requirements of this section commits an act of unprofessional conduct. The health professional's regulatory board may impose a civil penalty of not more than one thousand dollars in addition to other disciplinary action it takes.
- E. The regulatory board may deny the application of an applicant who does not comply with the notification requirements of this section.
- F. On request a health profession regulatory board shall provide an applicant or health professional with a list of misdemeanors that the applicant or health professional must report.

Disciplinary Actions and Updates Pharmacists

LeeAnn R. Scheer (S021314) – Consent agreement for civil penalty. The consent agreement includes a civil penalty of \$1,000.

Stanley P. Kudish (S010354) – Consent agreement and order for probation. The consent agreement includes five years of probation and a \$1,000 civil penalty.

Edmund Antone (S023632) – Consent agreement for civil penalty. License issued upon entry into consent agreement and payment of \$250 civil penalty.

Jessica E. Armaz (S016185) – Consent agreement for suspension and probation. License suspended for a minimum of six months. After suspension is lifted, license is placed on probation for four years and six months.

Christopher Shaun Stoffel (S019617) – Consent agreement and order for suspension. License suspended for a minimum of six months. License placed on probation for three years after suspension lifted. The order includes a \$40,000 civil penalty.

Ashwin Waghray (S015225) – Consent agreement for civil penalty. The consent agreement includes a \$5,000 civil penalty.

Trang Khanh Van (S021851) – Consent agreement for civil penalty. The consent agreement includes a \$500 civil penalty.

Lidia Teresa Dickinson (S011999) – Consent agreement for probation and civil penalty. License placed on probation for 12 months. \$4,000 civil penalty.

Thomas E. Frontz (S010694) – Consent agreement and order for probation. License placed on probation for a minimum of five years from March 1, 2018.

Danielle Avon Rogers (S013433) – Consent agreement and order for suspension. License suspended for six months. The consent agreement includes a \$2,000 civil penalty and nine hours of continuing education in ethics and the law.

Technicians

Edward William Lynn (T024492) – Consent agreement and order for voluntary surrender. License surrendered.

Nichole Lynn Stark (T062447) – Consent agreement for civil penalty. License issued upon entry into consent agreement and payment of \$250 civil penalty.

Drew Owen Browder (T045641) – Consent agreement for voluntary surrender. License surrendered.

Troy R. Robinson (T025818) – Consent agreement for civil penalty. The consent agreement includes a \$250 civil penalty.

Ellen Elson (T062589) – Consent agreement for civil penalty. License issued upon entry into consent agreement and payment of \$250 civil penalty.

Kyle Thomas Garcia (T062667) – Consent agreement for civil penalty. License issued upon entry into consent agreement and payment of \$250 civil penalty.

Gina Lorraine Turner (T057589) – Consent agreement for civil penalty. The consent agreement includes a \$250 civil penalty.

Glenn Matthew Gardner (T010445) – Consent agreement and order for voluntary surrender. License surrendered.

Julie A. Miller (T062668) – Consent agreement for civil penalty. License issued upon entry into consent agreement and payment of \$250 civil penalty.

Tracey Lynn Achey (T062745) – Consent agreement for civil penalty. License issued upon entry into consent agreement and payment of \$250 civil penalty.

Joseph Wheeler (T062746) – Consent agreement for civil penalty. License issued upon entry into consent agreement and payment of \$250 civil penalty.

Erika Browder (T062918) – Consent agreement for civil penalty. License issued upon entry into consent agreement and payment of \$250 civil penalty.

Tatiana Antoinette Andrews (T055407) – Consent agreement for civil penalty. Consent agreement includes a \$250 civil penalty.

Nadeen Hadi (T062978) – Consent agreement for civil penalty. License issued upon entry into consent agreement and payment of \$250 civil penalty.

Permits

Phoenix Children's Hospital Pharmacy (Y003489) – Consent agreement for civil penalty. The consent agreement includes a \$4,000 civil penalty.

Korman Healthcare Pharmacy (Y003805) – Consent agreement for civil penalty. The consent agreement includes a \$1,000 civil penalty.

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Valley of the Sun Pharmacy (Y006311) – Consent agreement for civil penalty. The consent agreement includes a \$1,000 civil penalty.

Serve n Save Pharmacy (SnS) (Y006811) – Consent agreement for civil penalty. The consent agreement includes a \$5,000 civil penalty.

Premier Pharmacy Services (Y006028) – Consent agreement for civil penalty. The consent agreement includes a \$9,000 civil penalty.

Melrose Pharmacy (Y004279) – Consent agreement for probation and civil penalty. The consent agreement includes a \$4,000 civil penalty.

Walgreens Drug #04139 (Y001427) – Consent agreement and order for civil penalty. The consent agreement includes a \$1,000 civil penalty.

Walgreens Drug #03447 (Y002747) – Consent agreement and order for civil penalty. The consent agreement includes a \$5,000 civil penalty.

Application Status Updates

Shawanna Amerson – Denial of application for licensure as a pharmacy technician trainee.

Katrease Johnson – Consent agreement for civil penalty. License will be issued upon payment of \$250 civil penalty.

Marlon Cambrell Bynum – Applicant denied licensure as a pharmacy technician trainee.

Alejandra Torres Cordova – Applicant denied licensure as a pharmacy technician trainee.

Linda York – Denial of application for licensure as a pharmacy technician.

Jacob Yutel – Findings of fact, conclusions of law, and Board order. Application for licensure as a pharmacy technician trainee denied.

Disciplinary Actions and Updates – Other Health Boards

Arizona Medical Board

Aaron Fernandes, MD #51606 – 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.

Diana H. Hydzik, MD #29302 – License revocation effective October 22, 2018.

Joseph B. Michelson, MD #54362 – License surrender effective October 23, 2018.

Robert S. Mindell, MD #18971 – Interim order for summary restriction is effective October 23, 2018. Respondent's license to practice allopathic medicine in the state of Arizona is summarily restricted in that he is prohibited from prescribing controlled substances (CS) in the state of Arizona pending the outcome of a formal hearing pursuant to A.R.S. §32-1451 (D).

Daniel M. Merck, MD #49945 – 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.

Shepherd G. Pryor, MD #33720 – 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.

Steven M. Rayle, MD #17733 – 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.

William F. Rees, MD #53589 – Respondent's license is reactivated with a letter of reprimand, and probation to include practice restriction. Respondent's practice is restricted in that he shall not act as the supervising physician for physician assistants as defined in A.R.S. §32-2501 (16) for the duration of this probation. Effective October 23, 2018.

Glenn G. Robertson, MD #33045 – License revocation effective December 14, 2018.

Marvin C. Schneider, MD #4036 – Interim practice restriction. Respondent is prohibited from prescribing CS in the state of Arizona until he requests release or modification from this order. The request must be accompanied by proof of completion of at least 10 hours of continuing medical education (CME) in a Board staff pre-approved, intensive, in-person CS prescribing course.

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 its affirmative permission to do so.

Kerry D. Malin, PA #5167 – Letter of reprimand with probation and restriction effective September 20, 2018. Respondent's practice is restricted in that he is prohibited from prescribing CS until he has completed the CME as stated in paragraph 3 (b) of the order, enters into an agreement with a Board-approved monitor to conduct chart reviews as stated in paragraph 2 (c) of the order, and provides Board staff satisfactory proof of compliance with these requirements. Final order terminates interim order.

Jacqueline J. Spiegel, PA #3415 – License surrender effective September 20, 2018.

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