



Arizona State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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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.

Corresponding Responsibility

By Jason Kwan, Pharmacy Intern, University of Arizona

The Drug Enforcement Administration (DEA) definition of corresponding responsibility (Title 21 Code of Federal Regulations (CFR) §1306.04) states:

A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section

309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.¹

The pharmacist is responsible for exercising professional judgment to determine whether the prescription is for a valid medical reason. A pharmacist is equally liable with the prescribing provider if drug abuse and diversion are involved. This corresponding responsibility is a pharmacist’s duty to uphold patient safety and advance care. Pharmacists are the last line of defense before a medication is dispensed to the patient. Pharmacists must be watchful in their pharmacies to identify red flags and prevent improper filling of controlled substances (CS).

Red flags include:²

- ◆ “Pattern prescribing” – when a prescription for the same drug and same quantity comes from the same doctor for multiple patients
- ◆ Prescribing improper combinations of CS such as the following without a legitimate medical reason:
 - ◇ Alprazolam, carisoprodol, hydrocodone
 - ◇ Alprazolam, carisoprodol, oxycodone
- ◆ Prescription comes from a prescriber at a distant location
- ◆ Patients paying cash for CS
- ◆ Fraudulent prescriptions
- ◆ Prescriptions written by doctors who normally do not prescribe CS in their area of specialty (radiology/pathology, etc)
- ◆ “Doctor shopping” – when patients have multiple prescribers and pharmacies
- ◆ Refilling controlled medications early and consistently

The Arizona Controlled Substance Prescription Monitoring Program provides an effective tool for pharmacists to track prescribing and dispensing of CS from a patient’s providers and pharmacies. Pharmacists are able to use the tool for support in determining if a CS should be filled if a patient presents with red flags. Pharmacists’ commitment to public safety plays an important role in curbing CS abuse and diversion.

References:


1. United States Department of Justice. Purpose of issue of prescription. 21 CFR §1306.04. https://www.deadiversion.usdoj.gov/21cfr/cfr/1306/1306_04.htm. Revised June 23, 2005. Diversion Control Division. Accessed November 9, 2016.

FDA Issues Final Rule Amending List of Drug Products That May Not Be Compounded

Food and Drug Administration (FDA) issued a final rule amending FDA's list of drug products that may not be compounded under certain sections of the Federal Food, Drug, and Cosmetic Act (FD&C Act) that allow the marketing of unapproved compounded drugs. Drug products on the list may not be compounded because the drug products have been withdrawn or removed from the market for safety or effectiveness reasons, indicates FDA. The list may be found in the Code of Federal Regulations at Title 21, Section 216.24, at www.ecfr.gov.

The final rule adds 24 types of drugs to the withdrawn or removed list; modifies the withdrawn or removed list to allow one type of drug product to be compounded under certain circumstances; and clarifies that the withdrawn or removed list applies to sections 503A and 503B of the FD&C Act. The final rule is available at www.gpo.gov/fdsys/pkg/FR-2016-10-07/pdf/2016-24333.pdf. FDA provides more information online at www.fda.gov/Drugs/DrugSafety/ucm524320.htm.

Selected Medication Risks to Manage in 2017

 *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.*

Some medication safety risks are painfully apparent in an organization, while many others lie dormant in the system until an error or adverse event draws attention to them. ISMP thought it would be useful to describe selected medication safety risks for organizations to manage in 2017 that might otherwise fall off the radar screen.

Environmental Factors, Workflow, and Staffing Patterns – Poor Quality Lighting

Lighting is a crucial aspect of the physical environment that has been linked to medication safety.¹ Poor quality lighting has often impaired the highly visual tasks associated with medication use, thus leading to medication errors. Examples include tubing misconnections due to low lighting in a patient's room, infusion pumps that have been misprogrammed because of dim backlighting on the screens, and product selection errors in the pharmacy and patient care units caused by low lighting under a pharmacy hood or shadows around an automated dispensing cabinet (ADC).

Despite existing guidelines for lighting in health care, it has been a challenge to implement optimal lighting conditions for prescribing, dispensing, and administering medications. Recent literature reviews found that little system-wide action has been

taken to increase staff awareness of the problem or improve the lighting.^{1,2} This is largely because the tasks associated with medication use are varied and carried out under diverse physical conditions and in differing locations, and because there are differences in an individual's light requirements based on visual acuity and age. With an ever-increasing population of older health care providers, eye fatigue from computer work and task complexity, small font sizes on medication labels, poor background contrast, and glare or shadows have taken their toll on visual accuracy.^{1,2}

Proper illumination improves both the accuracy and efficiency of medication-related tasks. Fluorescent cool white lamps or compact fluorescent lamps should be used in areas where critical tasks are performed, including on mobile medication carts, near ADCs, and in patients' rooms for nighttime administration of medications.^{3,4} Administration of medications at night under low lighting to avoid disturbing the patient is an unsafe practice and should be avoided. Adjustable 50-watt high-intensity task lights are recommended when difficult-to-read prescriptions and product labels are encountered.⁴ Illumination levels for computer order entry areas should be at least 75 foot-candles (fc), while 100-150 fc are needed when interpreting handwritten orders.⁴ Medication preparation areas, medication verification areas, and patient counseling areas should have illumination levels between 90-150 fc.⁴ Medication rooms should provide illumination at 100 fc.⁴ Lighting levels should be increased if the workforce has an average age above 45 years. A magnifying glass and task light together can also significantly improve accuracy³ and should be used on mobile medication carts (including those used with bar code medication verification systems)⁴ and near ADCs.

References:

1. Chaudhury H, Mahmood A, Valente M. The effect of environmental design on reducing nursing errors and increasing efficiency in acute care settings: a review and analysis of the literature. *Environ Behav.* 2009;41(6):755-786.
2. Graves K. *Nurses' Decision Making Processes About Lighting During Medication Administration* [dissertation]. Denton: Texas Woman's University College of Nursing; 2014.
3. Grasha AF. Psychosocial factors, workload, and risk of medication errors. *US Pharm.* 2002;27(4):HS32-52.
4. United States Pharmacopeial Convention. Chapter <1066> Physical environments that promote safe medication use. *Revision Bulletin.* October 1, 2010;2-6. www.ismp.org/sc?id=1664.

DEA to Decrease Manufacturing Amount of Opioid Controlled Substances in 2017

Drug Enforcement Administration (DEA) is reducing the amount of almost every Schedule II opiate and opioid medication that may be manufactured in 2017 by 25% or more. Other medicines were reduced by more, such as hydrocodone, which will be 66% of last year's level, indicates the DEA news release. DEA notes that demand for these opioid medicines has declined based on sales data from IMS Health, a company that provides insurance companies with data on prescriptions written and prescription medications sold in the United States.

The aggregate production quota (APQ) established by the final order is the total amount of a controlled substance (CS) necessary to meet the estimated medical, scientific, research, industrial, and export needs for the year and for the maintenance

News to a particular state or jurisdiction can only be ascertained
such state or jurisdiction.

of reserve stocks. The 2017 APQ has been reduced for oxycodone, hydrocodone, fentanyl, hydromorphone, morphine, and other such medications. Much of this reduction is attributed to the elimination of a 25% buffer that was added to the APQ annually in 2013 through 2016 to guard against shortages. The purpose of quotas is to provide an adequate and uninterrupted supply for legitimate medical need of the types of Schedule I and II CS that have a potential for abuse, while limiting the amounts available to prevent diversion.

Additional details may be found in the DEA news release available at www.dea.gov/divisions/hq/2016/hq100416.shtml and in the final order available at <https://www.gpo.gov/fdsys/pkg/FR-2016-10-05/pdf/2016-23988.pdf>.

New CDC Brochure Offers Pharmacists Tips for Addressing Prescription Opioid Abuse and Overdose

Centers for Disease Control and Prevention (CDC) released a brochure encouraging pharmacists, who are an essential part of the health care team, to help prevent opioid abuse and overdose. The brochure, “Pharmacists: On the Front Lines,” offers tips for communicating with patients who are receiving opioid therapy. In addition, the brochure offers tips on how to identify forged prescriptions and urges pharmacists to maintain collaborative working relationships with prescribers to improve patient outcomes. The brochure is available at www.cdc.gov/drugoverdose/pdf/pharmacists_brochure-a.pdf.

FDA Requires Boxed Warnings and Patient-Focused Medication Guides Indicating Serious Risks Related to Combined Use of Certain Opioid Medications and Benzodiazepines

FDA is requiring class-wide drug labeling changes to inform health care providers and patients of the serious risks associated with the combined use of certain opioid medications and benzodiazepines. Specifically, after an extensive review of the latest scientific evidence, FDA is requiring boxed warnings and patient-focused Medication Guides for prescription opioid analgesics, opioid-containing cough products, and benzodiazepines that provide information about the serious risks associated with using these medications at the same time. Risks include extreme sleepiness, respiratory depression, coma, and death.

FDA’s news release indicates the changes are part of the agency’s Opioids Action Plan, which focuses on policies aimed at reversing the prescription opioid abuse epidemic while providing patients in pain with access to effective and appropriate pain management. The public health crisis is evident through the significant rise of preventable overdose and death associated with the concurrent use of two drug classes, indicates FDA Commissioner Robert Califf, MD, in the press release, available at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm518697.htm.

FDA’s Division of Drug Information Offers CE Webinars for Students and Clinicians

FDA’s Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information presents a series of continuing education (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 drug shortages and prescription drug promotion. The webinars and presentation slides can be accessed on FDA’s website at www.fda.gov/DDIWebinars.

FDA Approves Labeling Changes for All Prescription Testosterone Products

In October 2016, FDA approved class-wide labeling changes for all prescription testosterone products regarding the risks associated with abuse and dependence of the drug. The changes include adding a new warning as well as updating the Abuse and Dependence section to include new safety information from published literature and case reports regarding the risks associated with abuse and dependence of testosterone and other anabolic androgenic steroids (AAS). The Anabolic Steroids Control Act of 1990 placed AAS, including testosterone, in Schedule III of the Controlled Substances Act.

Prescription testosterone products are FDA-approved as hormone replacement therapy for men who have low testosterone due to certain medical conditions. However, testosterone and other AAS are abused by adults and adolescents, including athletes and body builders, notes FDA. FDA indicates the new warning will “alert prescribers to the abuse potential of testosterone and the serious adverse outcomes, especially those related to heart and mental health that have been reported in association with testosterone/AAS abuse.” In addition, new labeling information in the Warning and Precautions section advises prescribers of the importance of measuring serum testosterone concentration if abuse is suspected.

FDA explains that abuse of testosterone, usually at doses higher than those typically prescribed and usually in conjunction with other AAS, is associated with serious safety risks affecting the heart, brain, liver, mental health, and endocrine system. Reported serious adverse outcomes include heart attack, heart failure, stroke, depression, hostility, aggression, liver toxicity, and male infertility. Individuals abusing high doses of testosterone have also reported withdrawal symptoms, such as depression, fatigue, irritability, loss of appetite, decreased libido, and insomnia. The FDA announcement is available at www.fda.gov/Drugs/DrugSafety/ucm526206.htm.

Latest FDA Drug Info Rounds Training Videos Available

Drug Info Rounds, a series of online videos by FDA, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the latest Drug Info Rounds video, “Extortion Scam,” pharmacists discuss steps a potential victim could take if they receive a call from individuals posing as FDA and DEA agents. Drug Info Rounds is developed with contributions from pharmacists in FDA’s CDER, Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.

2. Anti-Diversion Industry Working Group, National Association of Boards of Pharmacy. Red flags [video]. (2014). YouTube. <https://www.youtube.com/watch?v=WY9BDgcdxaM>. Published May 20, 2014. Accessed November 9, 2016.

Executive Order – Prescription Opioid; Initial Fill Limitation

The following text is from Executive Order 2016-06, Prescription Opioid; Initial Fill Limitation, signed by Governor Douglas A. Ducey.

WHEREAS, an estimated two million people in the United States have a prescription opioid use disorder; and **WHEREAS**, more than 14,000 people died from prescription opioid overdoses in 2014; and

WHEREAS, there has been a 300% increase in opioid prescription sales in the United States in the last fifteen years; and

WHEREAS, Arizona has the ninth highest rate of opioid deaths in the nation; and

WHEREAS, 401 people in Arizona died of prescription opioid overdoses in 2015; and

WHEREAS, in 2013 there were enough prescription pain medications dispensed to medicate every adult in Arizona around the clock for two weeks; and

WHEREAS, the majority of heroin users began by using prescription opioids; and

WHEREAS, addiction can affect people across all sections of society; and

WHEREAS, we must do all we can to not only treat those currently suffering from addiction, but to prevent future addictions; and

WHEREAS, the State of Arizona provides health insurance to hundreds of thousands of people through the State Medicaid and employee health plans.

NOW, THEREFORE, [with the virtue of the authority vested to Governor Douglas Ducey] by the Constitution and Laws of the State of Arizona [Governor Ducey] declare[s] the following:

1. The Directors of the Arizona Health Care Cost Containment System (AHCCCS) and the Arizona Department of Administration (ADOA) shall adopt any necessary policies and rules to limit the initial fill of any prescription opioid to no more than seven days.
2. The Directors of AHCCCS and ADOA shall adopt any necessary policies and rules to limit all initial and subsequent opioid prescriptions for minors to no more than seven days, except in the case of cancer, other chronic disease, or traumatic injury.

This Executive Order has been signed but will not be in effect until early 2017. Please be on the lookout for the effective date and any additional information on the Board website.

University of Arizona Poison and Drug Information Center

By Keith Boesen, PharmD, CSPI

The Board is pleased to announce a \$200,000 contribution to the University of Arizona's Arizona Poison and Drug Information Center (AzPDIC). This financial relationship began in 2012 when the Board approached the poison center to help maintain the program, which was struggling after state budget cuts in 2008. "The state board of pharmacy is excited to be able to support such a strong pharmacy run program that has helped so many people over the years," says Kam Gandhi, Board executive

director. In 2008, the state cut funding to the poison centers by 50%, quickly resulting in a deficit that put the AzPDIC at risk for closing. "The funds from the state board were critical to our survival in 2012, and the continued funding has allowed us to maintain our operations as well as increase the amount of training we provide," says Keith Boesen, director of the AzPDIC.

The AzPDIC was founded in 1953 by Dr Albert Picchioni, PhD, as the second poison center in the country. The AzPDIC has grown since those early days; we currently employ 12 pharmacists, with specific training in the field of toxicology to staff the phones 24/7, and six pharmacy interns. We also have six physician toxicologists to assist with more complicated medical cases, with one of them serving as our medical director. We also host the MotherToBaby Arizona service, staffed by genetic counselors to provide information about the safety of medications and other exposures during pregnancy and lactation.

The functions of a poison center can be summed up in four categories: public service, health care providers, education, and research.

As a **public service**, we are available 24/7, free and confidential to anyone at anytime. This includes the general public as well as health care providers. Our data collection tools and coordination with all the poison centers in the country make us uniquely equipped to identify exposures of public health concern either locally here in Arizona or nationally.

Once we receive the call, we play the role of **health care providers**. We work with our colleagues in Phoenix, AZ, at the Banner Poison and Drug Information Center, to provide a toxicology consult service for the state of Arizona. On average, every inbound call to the poison center results in two outbound calls. Many of these outbound calls are to follow-up with patients who we manage at home or to the health care facilities to provide treatment recommendations.

Education is a valuable part of the mission of poison centers. One of the only places where clinical toxicology is taught is at a poison center. In Tucson, AZ, we offer the only dual, two-year fellowship program, training pharmacists and physicians side by side. We also host over 60 medical and pharmacy residents and students to train for two- to six-week rotations. We also employ an outreach coordinator to provide poison prevention and medication safety to everyone in our service area. The poison centers in this country serve as the "toxicology universities" to teach this unique field of medicine.

Finally, **research** is an important part of the field of toxicology. From Dr Picchioni's early research on activated charcoal to today's phase III clinical trials with rattlesnake and scorpion antivenoms, we continue to further the knowledge of new treatments and interventions for toxic exposures.

As a leading pharmacy-run program, the AzPDIC's partnership with the Board of Pharmacy was a natural fit. We would not be where we are today, and we hope to continue this relationship well into the future. For more information about the AzPDIC, please visit us at www.azpoison.com.

Disciplinary Actions and Updates Pharmacists

For details on disciplinary actions, visit <https://pharmacy.az.gov/resources/disciplinary-actions/pharmacists>.

Yi-Ming Lee-Stalder, RPh (S008475) – Pay a civil penalty of \$500 within 60 days. Within six months complete an American Society of Health-System Pharmacists (ASHP) Guide to Chapter <797> Course 1 only.

John Makowsky, RPh (S011388) – Pay a civil penalty of \$500 within 180 days. Complete four hours of continuing education (CE) on medication errors/patient safety within six months.

Daniel Mason, RPh (S008062) – Pay a civil penalty of \$1,000 within 90 days. Complete eight hours of CE on patient safety.

Robin O’Nele, PharmD (S014246) – Must sign a new Pharmacists Assisting Pharmacists of Arizona (PAPA) contract, which shall extend for the entire term of the five-year probation.

Jay Sanes, RPh (S009333) – Pay a civil penalty of \$500 within 60 days. Complete eight hours of CE on patient safety.

Pharmacy Technicians

For details on disciplinary actions, visit <https://pharmacy.az.gov/resources/disciplinary-actions/technicians>.

Kristoffer Carzoli (T001397) – Pay a civil penalty of \$500 within 180 days. Complete four hours of CE within six months.

Ryan Hopkins (T029981) – Sign a contract with PAPA, which shall extend for the entire term of the five-year probation.

Luther Peterson (T042123) – Complete eight hours of CE on patient safety.

Richard Tenney (T014845) – Pay a civil penalty of \$500 within 60 days. Within six months complete an ASHP Guide to Chapter <797> Course 1 only.

Arizona Medical Board

Lloyd G. Barker, PA #2193 – 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 October 14, 2016.

Edward G. Blankstein, MD #10529 – Order for surrender of license and consent to the same. Respondent ordered to surrender his license for the practice of allopathic medicine in the state of Arizona immediately. Effective August 5, 2016.

Sailajah Janarathanan, MD #35946 – Order for letter of reprimand and probation and consent to the same. Respondent is issued a letter of reprimand. Respondent is placed on probation. Respondent’s practice is restricted in that she shall not practice medicine in the state of Arizona and is prohibited from prescribing any form of treatment including prescription medications until respondent completes the terms and conditions of the Michigan Board of Medicine’s order. Effective August 5, 2016.

Shakeel Aziz Kahn, MD #37896 – Interim findings of fact, conclusions of law and order for summary suspension of license. Respondent’s license to practice allopathic medicine in the state of Arizona is summarily suspended. 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 until receiving permission from the Board to do so. Effective August 5, 2016.

Michael Mahl, MD #12868 – Order for surrender of license and consent to the same. Respondent ordered to surrender his license for the practice of allopathic medicine in the state of Arizona immediately. Effective August 5, 2016.

Joshua Richard Marquis, PA #4588 – Order for surrender and consent to the same. Respondent ordered to surrender his license for the performance of health care tasks in the state of

Arizona and return his certificate of licensure to the Board. Effective September 22, 2016.

Rafael N. Mendoza, MD #27652 – 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. Effective August 15, 2016.

Earle Winston Moore, MD #47940 – Order for surrender of license and consent to the same. Respondent ordered to surrender his license for the practice of allopathic medicine in the state of Arizona immediately. Effective August 5, 2016.

Ethan Michael Philpott, MD #51541 – Interim consent agreement for practice limitation. Respondent is prohibited from engaging in the practice of medicine in the state of Arizona until he applies to the executive director and receives affirmative permission to do so. Effective October 18, 2016.

Laurance Silverman, MD #20780 – Order for surrender of license and consent to the same. Respondent ordered to surrender his license for the practice of allopathic medicine in the state of Arizona immediately. Effective November 10, 2016.

Jose A. Sosa-Roche, MD #18643 – Order for surrender of license and consent to the same. Respondent ordered to surrender his license for the practice of allopathic medicine in the state of Arizona immediately. Effective August 5, 2016.

David G. Stewart, MD #13560 – 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 affirmative permission to do so. Effective August 19, 2016.

Tyler Jonathan Suchala, MD #49271 – 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 affirmative permission to do so. Effective August 24, 2016.

Steven M. Young, PA #1634 – Order for surrender and consent to the same. Respondent ordered to surrender his license for the performance of health care tasks in the state of Arizona and return his certificate of licensure to the Board. Effective September 22, 2016.

Arizona State Board of Nursing

Sandra Kay Long, RN #RN079849 – Revocation. Advanced practice nurse and registered nurse licenses revoked. Effective October 21, 2016.

Arizona Board of Osteopathic Examiners in Medicine and Surgery

William Curtis Stonecipher, DO #0468 – Consent agreement for voluntary surrender of license to practice osteopathic medicine. Respondent’s license for the practice of osteopathic medicine in the state of Arizona is surrendered. Effective November 8, 2016.